OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
April 12, 2023
4:00pm

Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105

Viewing Access Only:
Please register for the webinar at:
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After registering, you will receive a confirmation email containing information about joining the webinar.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – April 12, 2023

DATE: April 5, 2023

NOTE: The DUR Board will meet at 4:00pm at the Oklahoma Health Care Authority (OHCA) at 4345 N. Lincoln Blvd. in Oklahoma City, Oklahoma.

There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.

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Enclosed are the following items related to the April meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit/SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – Appendix B

Action Item – Vote to Prior Authorize Briumvi™ (Ublituximab-xiiy) and Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)] and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications – Appendix C

Action Item – Vote to Prior Authorize Lamzede® (Velmanase Alfa) – Appendix D

Action Item – Vote to Prior Authorize Fylnetra® (Pegfilgrastim-pbbk), Rolvedon™ (Eflapegrastim-xnst), and Stimufend® (Pegfilgrastim-fpgk) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) – Appendix E

Action Item – Vote to Prior Authorize Airsupra™ (Albuterol/Budesonide) – Appendix F

Action Item – Vote to Prior Authorize Olpruva™ (Sodium Phenylbutyrate Pellets for Oral Suspension) and Pheburane® (Sodium Phenylbutyrate Oral Pellets) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications – Appendix G

Action Item – Vote to Prior Authorize Jaypirca™ (Pirtobrutinib) and Lunsumio™ (Mosunetuzumab-axgb) and Update the Approval Criteria for the Lymphoma Medications – Appendix H

Action Item – Annual Review of Hereditary Angioedema (HAE) Medications – Appendix I

Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Krazati® (Adagrasib) and Imjudo® (Tremelimumab-actl) – Appendix J

Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Brenzavvy™ (Bexagliflozin), Mounjaro® (Tirzepatide), and Tzield™ (Teplizumab-mzwv) – Appendix K

30-Day Notice to Prior Authorize Syfovre™ (Pegcetacoplan) – Appendix L

30-Day Notice to Prior Authorize Skyclarys™ (Omaveloxolone) – Appendix M

Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Ancobon® (Flucytosine) and Vivjoa® (Oteseconazole) – Appendix N

Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Konvomep™ (Omeprazole/Sodium Bicarbonate) – Appendix O

30-Day Notice to Prior Authorize Filspari™ (Sparsentan) – Appendix P

Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Doral® (Quazepam) – Appendix Q

Annual Review of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt) – Appendix R

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – Appendix S

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – April 12, 2023 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

NOTE: ***The DUR Board will meet at 4:00pm at OHCA (see address above). There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.***

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Jennifer de los Angeles –	participating in person
Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person

Viewing Access Only via Zoom:

Please register for the meeting at:
https://zoom.us/webinar/register/WN_73z8ERX7Sv-KeQGP3GVqPg
After registering, you will receive a confirmation email containing information about joining the webinar.

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 952 7560 1667
Passcode: 69395211

Public Comment for Meeting:

- Speakers who wish to sign up for public comment at the OHCA DUR Board meeting may do so in writing by visiting the DUR Board page on the OHCA website at www.oklahoma.gov/ohca/about/boards-and-committees/drug-utilization-review/dur-board and completing the Speaker Registration Form. Completed Speaker Registration forms should be submitted to DURPublicComment@okhca.org. Forms must be received after the DUR Board agenda has been posted and no later than 24 hours before the meeting.
- The DUR Board meeting will allow public comment and time will be limited to 40 minutes total for all speakers during the meeting. Each speaker will be given 5 minutes to speak at the public hearing. If more than 8 speakers properly request to speak, time will be divided evenly.
- Only 1 speaker per manufacturer will be allowed.
- Any speakers who sign up for public comment must attend the DUR Board meeting in person at OHCA (see above address). Public comment through Zoom will not be allowed for the DUR Board meeting.

Items to be presented by Dr. Muchmore, Chairman:

2. **Public Comment Forum**
   A. Acknowledgement of Speakers for Public Comment

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. March 8, 2023 DUR Board Meeting Minutes
   B. March 8, 2023 DUR Board Recommendations Memorandum

Items to be presented by Dr. Kottoor, Dr. Travers, Dr. Muchmore, Chairman:

4. **Update on Medication Coverage Authorization Unit/SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – See Appendix B**
   A. Pharmacy Help Desk Activity for March 2023
   B. Medication Coverage Activity for March 2023
   C. SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

Items to be presented by Dr. O'Halloran, Dr. Muchmore, Chairman:

5. **Action Item – Vote to Prior Authorize Briumvi™ (Ublituximab-xiiy) and Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)] and Update the Approval Criteria for Multiple Sclerosis (MS) Medications – See Appendix C**
   A. Market News and Updates
   B. Briumvi™ (Ublituximab-xiiy) Product Summary
   C. Cost Comparison: Fingolimod Products
   D. College of Pharmacy Recommendations

Items to be presented by Dr. O'Halloran, Dr. Muchmore, Chairman:

6. **Action Item – Vote to Prior Authorize Lamzede® (Velmanase Alfa) – See Appendix D**
   A. Lamzede® (Velmanase Alfa) Product Summary
   B. College of Pharmacy Recommendations

Items to be presented by Dr. Moss, Dr. Muchmore, Chairman:

7. **Action Item – Vote to Prior Authorize Rolvedon™ (Eflapegrastim-xnst) and Stimufend® (Pegfilgrastim-fpgk) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) – See Appendix E**
   A. Market News and Updates
   B. Cost Comparison
   C. College of Pharmacy Recommendations

Items to be presented by Dr. Kottoor, Dr. Muchmore, Chairman:

8. **Action Item – Vote to Prior Authorize Airsupra™ (Albuterol/Budesonide) – See Appendix F**
   A. Market News and Updates
   B. Airsupra™ (Albuterol/Budesonide) Inhalation Aerosol Product Summary
   C. College of Pharmacy Recommendations

Items to be presented by Dr. Reynolds, Dr. Muchmore, Chairman:

9. **Action Item – Vote to Prior Authorize Olpruva™ (Sodium Phenylbutyrate Pellets for Oral Suspension) and Pheburane® (Sodium Phenylbutyrate Oral Pellets) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications – See Appendix G**
   A. Market News and Updates
   B. Cost Comparison: UCD Medications
   C. College of Pharmacy Recommendations

Items to be presented by Dr. Borders, Dr. Muchmore, Chairman:

10. **Action Item – Vote to Prior Authorize Jaypirca™ (Pirtobrutinib) and Lunsumio™ (Mosunetuzumab-axgb) and Update the Approval Criteria for the Lymphoma Medications– See Appendix H**
    A. Market News and Updates
    B. Jaypirca™ (Pirtobrutinib) Product Summary
    C. Lunsumio™ (Mosunetuzumab-axgb) Product Summary
    D. College of Pharmacy Recommendations

Items to be presented by Dr. Reynolds, Dr. Muchmore, Chairman:

11. **Action Item – Annual Review of Hereditary Angioedema (HAE) Medications – See Appendix I**
    A. Current Prior Authorization Criteria
    B. Utilization of HAE Medications

C. Prior Authorization of HAE Medications
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of HAE Medications

Items to be presented by Dr. Borders, Dr. Muchmore, Chairman:

12. Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Krazati® (Adagrasib)and Imjudo® (Tremelimumab-actl) – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of Lung Cancer Medications
C. Prior Authorization of Lung Cancer Medications
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Lung Cancer Medications

Items to be presented by Dr. O'Halloran, Dr. Muchmore, Chairman:

13. Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Brenzavvy™ (Bexagliflozin), Mounjaro® (Tirzepatide), and Tzield™ (Teplizumab-mzwv) – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Anti-Diabetic Medications and Kerendia® (Finerenone)
C. Prior Authorization of Anti-Diabetic Medications and Kerendia® (Finerenone)
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Anti-Diabetic Medications and Kerendia® (Finerenone)

Items to be presented by Dr. Moss, Dr. Muchmore, Chairman:

14. 30-Day Notice to Prior Authorize Syfovre™ (Pegcetacoplan) – See Appendix L

A. Introduction
B. Syfovre™ (Pegcetacoplan) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. O'Halloran, Dr. Muchmore, Chairman:

15. 30-Day Notice to Prior Authorize Skyclarys™ (Omaveloxolone) – See Appendix M

A. Introduction
B. Skyclarys™ (Omaveloxolone) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. Reynolds, Dr. Muchmore, Chairman:

16. **Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Ancobon® (Flucytosine) and Vivjoa® (Oteseconazole) – See Appendix N**

A. Current Prior Authorization Criteria
B. Utilization of Systemic Antifungal Medications
C. Prior Authorization of Systemic Antifungal Medications
D. Market News and Updates
E. Vivjoa® (Oteseconazole) Product Summary
F. Cost Comparison: Recurrent Vulvovaginal Candidiasis (RVVC) Treatments
G. College of Pharmacy Recommendations
H. Utilization Details of Antifungal Medications

Items to be presented by Dr. O'Halloran, Dr. Muchmore, Chairman:

17. **Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Konvomep™ (Omeprazole/Sodium Bicarbonate) – See Appendix O**

A. Current Prior Authorization Criteria
B. Utilization of Anti-Ulcer Medications
C. Prior Authorization of Anti-Ulcer Medications
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Anti-Ulcer Medications

Items to be presented by Dr. Moss, Dr. Muchmore, Chairman:

18. **30-Day Notice to Prior Authorize Filspari™ (Sparsentan) – See Appendix P**

A. Introduction
B. Filspari™ (Sparsentan) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. Kottoor, Dr. Muchmore, Chairman:

19. **Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Doral® (Quazepam) – See Appendix Q**

A. Current Prior Authorization Criteria
B. Utilization of Insomnia Medications
C. Prior Authorization of Insomnia Medications
D. Market News and Updates
E. Doral® (Quazepam) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Insomnia Medications

Items to be presented by Dr. Kottoor, Dr. Muchmore, Chairman:

20. **Annual Review of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt) – See Appendix R**

A. Current Prior Authorization Criteria
B. Utilization of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt)
C. Prior Authorization of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt)
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt)

Items to be presented by Dr. Kottoor, Dr. Muchmore, Chairman:

21. U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – See Appendix S

Items to be presented by Dr. Adams, Dr. Muchmore, Chairman:

22. Future Business* (Upcoming Product and Class Reviews)
No DUR Board meeting scheduled for May 2023.

A. Annual Review of the SoonerCare Pharmacy Benefit
B. Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications
C. Atypical Antipsychotic Medications
D. Hemophilia Medications

*Future product and class reviews subject to change.

23. Adjournment

NOTE: An analysis of the atypical [Aged, Blind, and Disabled (ABD)] patient subgroup of the Oklahoma Medicaid population has been performed pertaining to all recommendations included in this DUR Board meeting packet to ensure fair and knowledgeable deliberation of the potential impact of the recommendations on this patient population.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING MARCH 8, 2023

DUR BOARD MEMBERS:	PRESENT	ABSENT
Jennifer de los Angeles, Pharm.D., BCOP		X
Kenneth Foster, MHS, PA-C	X	
Megan A. Hanner, D.O.	X	
Lynn Mitchell, M.D.; Vice Chairwoman		X
John Muchmore, M.D.; Ph.D.; Chairman	X	
Lee Muñoz, D.Ph.	X	
James Osborne, Pharm.D.		X
Edna Patatanian, Pharm.D., FASHP	X	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Thara Kottoor, Pharm.D.; Pharmacy Resident	X	
Morgan Masterson, Pharm.D; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Jo'Nel Reynolds, Pharm.D.; Clinical Pharmacist	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Tad Autry Pharm.D., BCPS, BCOP		X
Allison Baxley, Pharm.D., BCOP		X
Emily Borders, Pharm.D., BCOP	X	
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.		X
Victoria Jones, Pharm.D.		X
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.	X	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief of Staff		X
Kevin Corbett, C.P.A.; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	

Josh Holloway, J.D.; Deputy General Counsel	X	
Brandon Keppner; Chief Operating Officer		X
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Interim Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Toney Welborn, M.D., MPH, MS; Medical Director		X

OTHERS PRESENT:	
Mike Scott	Corey Hicks, Horizon Therapeutics
Joe Payne, Horizon Therapeutics	Frank Alvarado, Johnson & Johnson
Rhonda Clark, Indivior	Ann Nelson, Vertex
Bob Atkins, Biogen	Kimberly Brackett, AbbVie
Marc Parker, Sunovion	Dr. John Kingrey, Integris Health
Emily Frans, Integris Health	Brent Parker, Merck
Doug Pierce, Genentech	Shellie Keast, Mercer
Amanda Nowakowski, ViiV	Dave Poskey, UCB
Todd Ness, AbbVie	Dr. Anne Tsai, OUHSC
Eric Kimelblatt, Viking Healthcare	Jinga Bhalla, AstraZeneca
Roger Grotzinger, Bristol Myers Squibb	Lee Stout, Chiesi
Lauren Mangum, Recordati	Robert Greely, Biogen
Jonathan Rosenblatt, Horizon Therapeutics	Burl Beasly, OMES
Fred Bero, Horizon Therapeutics	Wendi Chandler
Abby Hata, Horizon Therapeutics	Tari Garza, Johnson & Johnson
Melissa Abbott, Eisai	Jeff Knappen, Karuna Therapeutics
Shelly Nickerson, Marinus	Todd Dickerson, Jazz Pharmaceuticals
Lindsey Walter, Novartis	John Stancil, Artia Solutions
Gina Heinen, Novo Nordisk	Phillip Lohec, Viatris
Aaron Austin, Takeda	Robin Selsor, Aimmune
Lynne Bouffard, Horizon Therapeutics	

PRESENT FOR PUBLIC COMMENT:	
Dr. John Kingrey, Integris Health	Corey Hicks, Horizon Therapeutics
Dr. Anne Tsai, OUHSC	

AGENDA ITEM NO. 1: **CALL TO ORDER**

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:00pm. Roll call by Dr. Wilcox established the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**

2A: AGENDA ITEM NO. 6 DR. JOHN KINGREY

2B: AGENDA ITEM NO. 15 COREY HICKS

2C: AGENDA ITEM NO. 15 DR. ANNE TSAI

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MEETING MINUTES**

3A: FEBRUARY 8, 2023 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore
Dr. Muñoz moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/SPRING 2023 PIPELINE UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR FEBRUARY 2023

4B: MEDICATION COVERAGE ACTIVITY FOR FEBRUARY 2023

4C: SPRING 2023 PIPELINE UPDATE

Materials included in agenda packet; presented by Dr. Moss, Dr. Kottoor

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE BRIMONIDINE 0.33% TOPICAL GEL (GENERIC MIRVASO®), VTAMA® (TAPINAROF), AND ZORYVE™ (ROFLUMILAST) AND UPDATE THE APPROVAL CRITERIA FOR TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS**

5A: MARKET NEWS AND UPDATES

5B: PRODUCT SUMMARIES

5C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Kottoor
Dr. Muñoz moved to approve; seconded by Dr. Hanner

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE TADLIQ® (TADALAFIL ORAL SUSPENSION) AND TYVASO DPI® (TREPROSTINIL POWDER FOR INHALATION) AND UPDATE THE APPROVAL CRITERIA FOR THE PULMONARY HYPERTENSION MEDICATIONS**

6A: MARKET NEWS AND UPDATES

6B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE ZONISADE™ (ZONISAMIDE ORAL SUSPENSION) AND ZTALMY® (GANAXOLONE) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTICONVULSANTS**

7A: MARKET NEWS AND UPDATES

7B: ZTALMY® (GANAXOLONE) PRODUCT SUMMARY

7C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Hanner

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE REZLIDHIA™ (OLUTASIDENIB) AND UPDATE THE APPROVAL CRITERIA FOR THE LEUKEMIA MEDICATIONS**

8A: MARKET NEWS AND UPDATES

8B: REZLIDHIA™ (OLUTASIDENIB) PRODUCT SUMMARY

8C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders
Dr. Muñoz moved to approve; seconded by Dr. Hanner

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> ANNUAL REVIEW OF LYMPHOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE JAYPIRCA™ (PIRTOBRUTINIB) AND LUNSUMIO™ (MOSUNETUZUMAB-AXGB)

9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF LYMPHOMA MEDICATIONS
9C: PRIOR AUTHORIZATION OF LYMPHOMA MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: JAYPIRCA™ (PIRTOBRUTINIB) PRODUCT SUMMARY
9F: LUNSUMIO™ (MOSUNETUZUMAB-AXGB) PRODUCT SUMMARY
9G: COLLEGE OF PHARMACY RECOMMENDATIONS
9H: UTILIZATION DETAILS OF LYMPHOMA MEDICATIONS

Materials included in agenda packet; presented by Dr. Borders

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 10:</u> ANNUAL REVIEW OF GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND 30-DAY NOTICE TO PRIOR AUTHORIZE ROLVEDON™ (EFLAPEGRASTIM-XNST) AND STIMUFEND® (PEGFILGRASTIM-FPGK)

10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF G-CSFS
10C: PRIOR AUTHORIZATION OF G-CSFS
10D: MARKET NEWS AND UPDATES
10E: COST COMPARISON
10F: COLLEGE OF PHARMACY RECOMMENDATIONS
10G: UTILIZATION DETAILS OF G-CSFS

Materials included in agenda packet; presented by Dr. Moss

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)

11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
11C: PRIOR AUTHORIZATION OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 12:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE LAMZEDE® (VELMANASE ALFA-TYCV)

12A: INTRODUCTION
12B: LAMZEDE® (VELMANASE ALFA-TYCV) PRODUCT SUMMARY
12C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF MULTIPLE SCLEROSIS (MS) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BRIUMVI™

(UBLITUXIMAB-XIIY) AND TASCENSO ODT® [FINGOLIMOD ORALLY DISINTEGRATING TABLET (ODT)]
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF MS MEDICATIONS
13C: PRIOR AUTHORIZATION OF MS MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: BRIUMVI™ (UBLITUXIMAB-XIIY) PRODUCT SUMMARY
13F: COST COMPARISON: FINGOLIMOD PRODUCTS
13G: COLLEGE OF PHARMACY RECOMMENDATIONS
13H: UTILIZATION DETAILS OF MS MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

AGENDA ITEM NO. 14: ANNUAL REVIEW OF SHORT-ACTING BETA2 AGONISTS (SABAS) AND 30-DAY NOTICE TO PRIOR AUTHORIZE AIRSUPRA™ (ALBUTEROL/BUDESONIDE)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF SABAS
14C: PRIOR AUTHORIZATION OF SABAS
14D: MARKET NEWS AND UPDATES
14E: AIRSUPRA™ (ALBUTEROL/BUDESONIDE) PRODUCT SUMMART
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF SABAS
Materials included in agenda packet; presented by Dr. Kottoor
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

AGENDA ITEM NO. 15: ANNUAL REVIEW OF UREA CYCLE DISORDER (UCD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE OLPRUVA™ (SODIUM PHENYLBUTYRATE PELLETS FOR ORAL SUSPENSION) AND PHEBURANE® (SODIUM PHENYLBUTYRATE ORAL PELLETS)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF UCD MEDICATIONS
15C: PRIOR AUTHORIZATION OF UCD MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: COST COMPARISON: UCD MEDICATIONS
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF UCD MEDICATIONS
Materials included in agenda packet; presented by Dr. Reynolds
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

AGENDA ITEM NO. 16: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
17A: ANTI-DIABETIC MEDICATIONS
17B: ANTI-EMETIC MEDICATIONS
17C: LUNG CANCER MEDICATIONS
17D: SYSTEMIC ANTIFUNGAL MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: **ADJOURNMENT**

The meeting was adjourned at 5:47pm.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: March 10, 2023

To: Terry Cothran, D.Ph.
Pharmacy Director
Oklahoma Health Care Authority

From: Michyla Adams, Pharm.D.
Drug Utilization Review (DUR) Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting on March 8, 2023

Recommendation 1: Spring 2023 Pipeline Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Brimonidine 0.33% Topical Gel (Generic Mirvaso®), Vtama® (Tapinarof), and Zoryve™ (Roflumilast) and Update the Approval Criteria for the Topical Acne, Psoriasis, and Rosacea Products

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends the prior authorization of brimonidine 0.33% topical gel (generic Mirvaso®), Vtama® (tapinarof 1% cream), and Zoryve™ (roflumilast 0.3% cream) with the following criteria (shown in red):

Brimonidine 0.33% Topical Gel (Generic Mirvaso®) Approval Criteria:

1. An FDA approved diagnosis of persistent (non-transient) facial erythema of rosacea; and
2. Member must be 18 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot utilize clindamycin topical solution (generic), metronidazole 0.75% topical gel and cream, erythromycin 2% topical solution, oral isotretinoin medications, or other generically available preferred oral or topical antibiotic products must be provided; and

4. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
5. Brand name Mirvaso® is not a covered product; and
6. A quantity limit of 30 grams per 30 days will apply.

Vtama® (Tapinarof 1% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 18 years of age or older; and
3. Member must have a body surface area (BSA) involvement of ≤20%; and
4. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
   a. An ultra-high to high potency topical corticosteroid (TCS); or
   b. A generic topical calcipotriene product; or
   c. A topical tazarotene product; and
6. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 60 grams per 30 days will apply.

Zoryve™ (Roflumilast 0.3% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 12 years of age or older; and
3. Member must have a body surface area (BSA) involvement of ≤20%; and
4. Member must not have moderate-to-severe hepatic impairment (Child-Pugh B or C); and
5. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
6. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
   a. An ultra-high to high potency topical corticosteroid (TCS); or
   b. A generic topical calcipotriene product; or
   c. A topical tazarotene product; and
7. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 grams per 30 days will apply.

Additionally, the College of Pharmacy recommends updating the approval criteria for Amzeeq® (minocycline 4% topical foam) and Tazorac® (tazarotene cream and gel) based on the new tazarotene generic approvals and product availability (changes shown in red):

Amzeeq® (Minocycline 4% Topical Foam) Approval Criteria:

1. An FDA approved diagnosis of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and
3. Amzeeq® will not be covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution, clindamycin 1% topical solution, benzoyl peroxide, ~~brand name Tazorac®,~~ preferred tazarotene formulations, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
5. A quantity limit of 30 grams per 30 days will apply.

Tazorac® (Tazarotene Cream and Gel) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris or plaque psoriasis; and
2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
3. For the diagnosis of acne vulgaris, the following must be met:
   a. Member must be 20 years of age or younger; and
   b. ~~Tazorac® 0.1% cream, Tazorac® 0.05% gel, Tazorac® 0.1% gel, and~~ tazarotene 0.1% cream will not require prior authorization for members 20 years of age or younger; and
4. Tazarotene 0.05% gel and tazarotene 0.1% gel will require a patient specific, clinically significant reason why the member cannot use tazarotene 0.1% cream, which is available without prior authorization for members 20 years of age and younger; and
5. A quantity limit of 100 grams per 30 days will apply.

Recommendation 3: Vote to Prior Authorize Tadliq® (Tadalafil Oral Suspension) and Tyvaso DPI® (Treprostinil Powder for Inhalation) and Update the Approval Criteria for the Pulmonary Hypertension Medications

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends the prior authorization of Tadliq® (tadalafil oral suspension) and Tyvaso DPI® (treprostinil powder for inhalation) with the following criteria (shown in red):

Tadliq® (Tadalafil Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and

3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension must be provided; and
4. An age restriction will apply. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member cannot use generic tadalafil 20mg oral tablets, even when the tablets are crushed; and
5. A quantity limit of 300mL per 30 days (2 bottles) will apply.

Tyvaso DPI® (Treprostinil Powder for Inhalation) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Pulmonary arterial hypertension (PAH); or
    b. Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and
        i. Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. For a diagnosis of PAH:
    a. Member must have previous failed trials of at least 1 of each of the following categories:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. A patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and
4. For a diagnosis of PH-ILD, a patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.

Additionally, the College of Pharmacy recommends updating the approval criteria for Orenitram® (treprostinil) to be more consistent with FDA approved dosing and clinical practice (changes shown in red):

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
    a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A quantity limit of ~~90~~ 180 tablets per 30 days will apply.

Lastly, the College of Pharmacy recommends removing the approval criteria for generic ambrisentan, based on net costs (changes shown in red):

~~**Generic Ambrisentan (Letairis®) Approval Criteria:**~~

~~1. A patient-specific, clinically significant reason the member cannot use the brand formulation must be provided.~~

Recommendation 4: Vote to Prior Authorize Zonisade™ (Zonisamide Oral Suspension) and Ztalmy® (Ganaxolone) and Update the Approval Criteria for the Anticonvulsants

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends the prior authorization of Ztalmy® (ganaxolone) and Zonisade™ (zonisamide oral suspension) with the following criteria (shown in red):

Ztalmy® (Ganaxolone) Approval Criteria:

1. An FDA approved diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD); and
    a. Diagnosis must be confirmed by genetic testing identifying a mutation in the CDKL5 gene that is pathogenic or likely pathogenic; and
2. Member must be 2 years of age or older; and
3. The initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must have failed at least 2 other anticonvulsants; and
5. Members currently stable on Ztalmy® and who have a CDD diagnosis confirmed by genetic testing will be approved for continuation of therapy; and
6. The member's recent weight (kg), taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
7. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
8. Subsequent approvals will be for the duration of 1 year; and
9. A quantity limit of 1,100mL per 30 days will apply.

Zonisade™ (Zonisamide Oral Suspension) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of partial-onset seizures; and
2. A patient-specific, clinically significant reason why the member cannot use zonisamide capsules must be provided; and
3. A quantity limit of 900mL per 30 days will apply.

Additionally, the College of Pharmacy recommends updating the Fintepla® (fenfluramine) approval criteria based on the new FDA approved indication (changes shown in red):

Fintepla® (Fenfluramine) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Dravet syndrome; or
   b. Lennox-Gastaut syndrome (LGS); and
2. Member must be 2 years of age or older; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must not be taking monoamine oxidase inhibitors within 14 days of administration of Fintepla®; and
5. Prescriber must verify the member's blood pressure will be monitored; and
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Fintepla® therapy and throughout treatment; and
7. For a diagnosis of Dravet syndrome, the member must have failed or be inadequately controlled with at least 2 other anticonvulsants; and
8. For a diagnosis of LGS, the member must have failed or be inadequately controlled with at least 3 other anticonvulsants; and
9. Pharmacy and provider must be certified in the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Fintepla® REMS program; and
11. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
12. Prescriber must verify that dose titration and maximum maintenance dose will be followed according to package labeling based on member weight and concomitant medications; and
13. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
14. A quantity limit of 360mL per 30 days will apply.

The College of Pharmacy also recommends updating the Diacomit® (stiripentol) approval criteria based on the new FDA approved age expansion (changes shown in red):

Diacomit® (Stiripentol) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Dravet syndrome ~~in members 2 years of age and older~~; and
2. Member must be 6 months of age or older and weigh ≥7kg; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must have failed or be inadequately controlled with clobazam and valproate; and

5. Member must take clobazam and valproate concomitantly with Diacomit® or a reason why concomitant clobazam and valproate are not appropriate for the member must be provided; and
6. Members currently stable on Diacomit® and who have a seizure diagnosis will be approved for continuation of therapy; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. For Diacomit® powder for oral suspension, an age restriction of 12 years and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral capsule formulation; and
9. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Finally, the College of Pharmacy recommends updating the Banzel® (rufinamide) and Trokendi XR® [topiramate extended-release (ER)] approval criteria based on net costs (changes shown in red):

Banzel® (Rufinamide) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); and
2. Initial prescription must be written by a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Authorization of generic rufinamide (in place of brand Banzel®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
5. Members currently stable on Banzel® (rufinamide) and who have a seizure diagnosis will be approved for continuation of therapy.

Trokendi XR® [Topiramate Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
   b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
   c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and
3. ~~A patient-specific, clinically significant reason why the member cannot use Qudexy® XR (topiramate ER) must be provided; and~~
4. Members currently stable on Trokendi XR® (topiramate ER) and who have a seizure diagnosis will be approved for continuation of therapy; and

5. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (200mg).

Recommendation 5: Vote to Prior Authorize Rezlidhia™ (Olutasidenib) and Update the Approval Criteria for the Leukemia Medications

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends the prior authorization of Rezlidhia™ (olutasidenib) with the following criteria (shown in red):

Rezlidhia™ (Olutasidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Relapsed/refractory AML; and
    a. As a single agent; and
    b. Isocitrate dehydrogenase-1 (IDH1) mutation.

Additionally, the College of Pharmacy recommends updating the approval criteria for Imbruvica® (ibrutinib), Kymriah® (tisagenlecleucel), and Tibsovo® (ivosidenib) based on recent FDA approvals and to be consistent with the other chimeric antigen receptor (CAR) T-cell therapies (changes shown in red):

Imbruvica® (Ibrutinib) Approval Criteria [Chronic Graft-Versus-Host Disease (cGVHD) Diagnosis]:

1. Failure of 1 or more lines of therapy; and
2. Member must be 1 year of age or older; and
3. For members younger than 12 years of age:
    a. The member's current body surface area (BSA) must be provided; and
    b. Requests for use of the 70mg capsule formulation will require a patient-specific, clinically significant reason why the member cannot use the 70mg/mL oral suspension formulation.

Kymriah® (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Relapsed/refractory disease; and
3. Member must be 18 years of age or older; and
4. Member must not have primary central nervous system lymphoma; and
5. Member must have had ≥2 lines of therapy; and
6. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells, must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and must

comply with the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) requirements; and
7. Approvals will be for 1 dose per member per lifetime.

Tibsovo® (Ivosidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
   a. Member meets 1 of the following:
      i. Member is 75 years of age or older; or
      ii. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
   b. As a single agent or in combination with azacitidine; and
   c. Isocitrate dehydrogenase-1 (IDH1) mutation; or
2. Relapsed/refractory AML; and
   a. As a single agent; and
   b. IDH1 mutation.

Lastly, the College of Pharmacy recommends the removal of the Zydelig® (idelalisib) approval criteria for the FL and SLL indications based on the FDA withdrawal of the previous accelerated approvals for those indications (changes shown in red):

Zydelig® (Idelalisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)~~/Small Lymphocytic Lymphoma (SLL)~~ Diagnosis]:

1. Relapsed/refractory disease; and
2. In combination with rituximab ~~or rituximab/bendamustine~~; or
3. As a single agent.

~~**Zydelig® (Idelalisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

~~1. Grade 1 to 2 FL; and~~
~~2. As second-line or subsequent therapy for refractory or progressive disease; and~~
~~3. Refractory to both alkylator and rituximab therapy.~~

Recommendation 6: Annual Review of Lymphoma Medications and 30-Day Notice to Prior Authorize Jaypirca™ (Pirtobrutinib) and Lunsumio™ (Mosunetuzumab-axgb)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2023.

Recommendation 7: Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and 30-Day Notice to Prior Authorize Rolvedon™ (Eflapegrastim-xnst) and Stimufend® (Pegfilgrastim-fpgk)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2023.

Recommendation 8: Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide)

NO ACTION REQUIRED.

Recommendation 9: 30-Day Notice to Prior Authorize Lamzede® (Velmanase Alfa-tycv)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2023.

Recommendation 10: Annual Review of Multiple Sclerosis (MS) Medications and 30-Day Notice to Prior Authorize Briumvi™ (Ublituximab-xiiy) and Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)]

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2023.

Recommendation 11: Annual Review of Short-Acting Beta$_2$ Agonists (SABAs) and 30-Day Notice to Prior Authorize Airsupra™ (Albuterol/ Budesonide)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2023.

Recommendation 12: Annual Review of Urea Cycle Disorder (UCD) Medications and 30-Day Notice to Prior Authorize Olpruva™ (Sodium Phenylbutyrate) and Pheburane® (Sodium Phenylbutyrate)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2023.

Recommendation 13: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

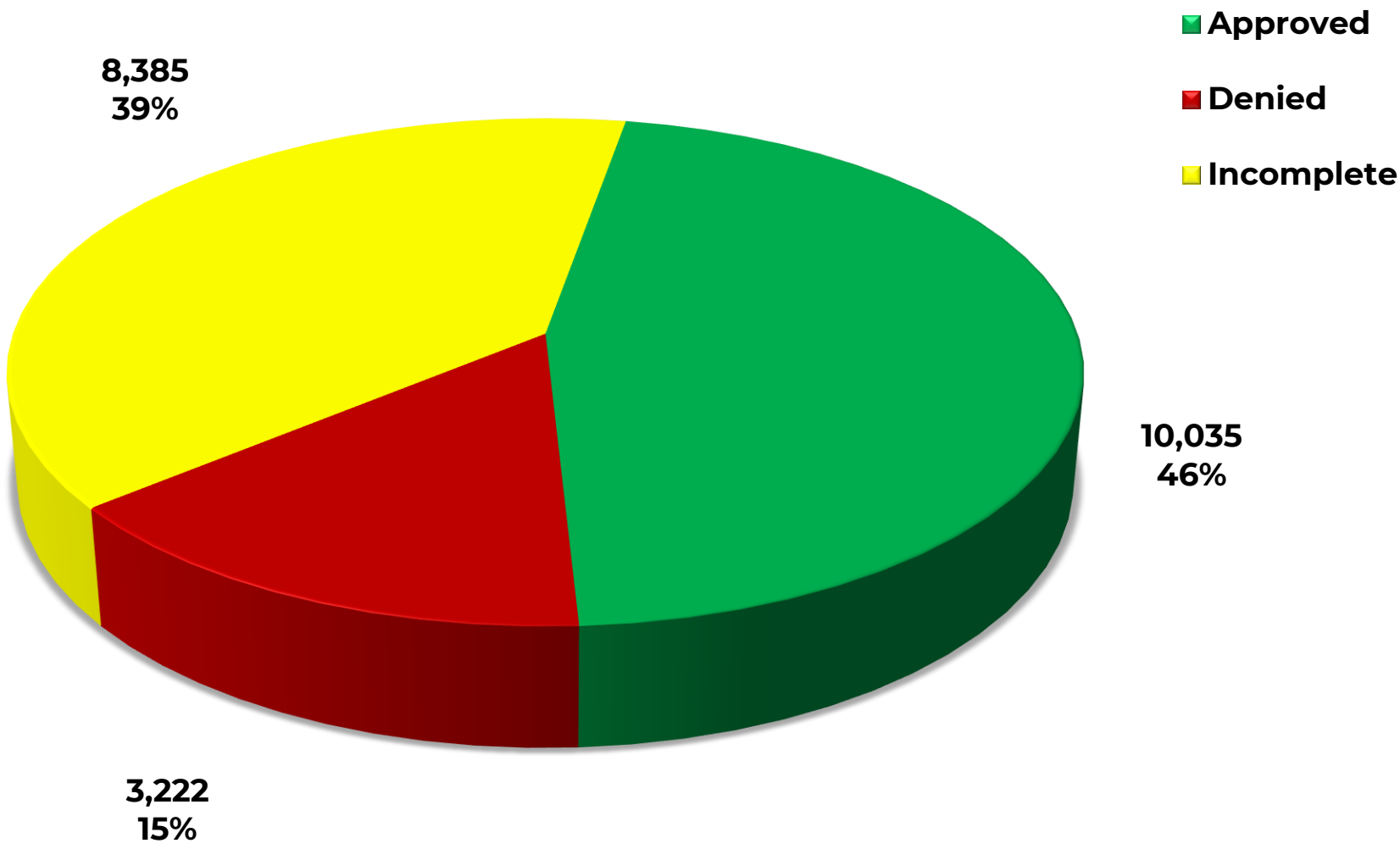
NO ACTION REQUIRED.

Recommendation 14: Future Business

NO ACTION REQUIRED.

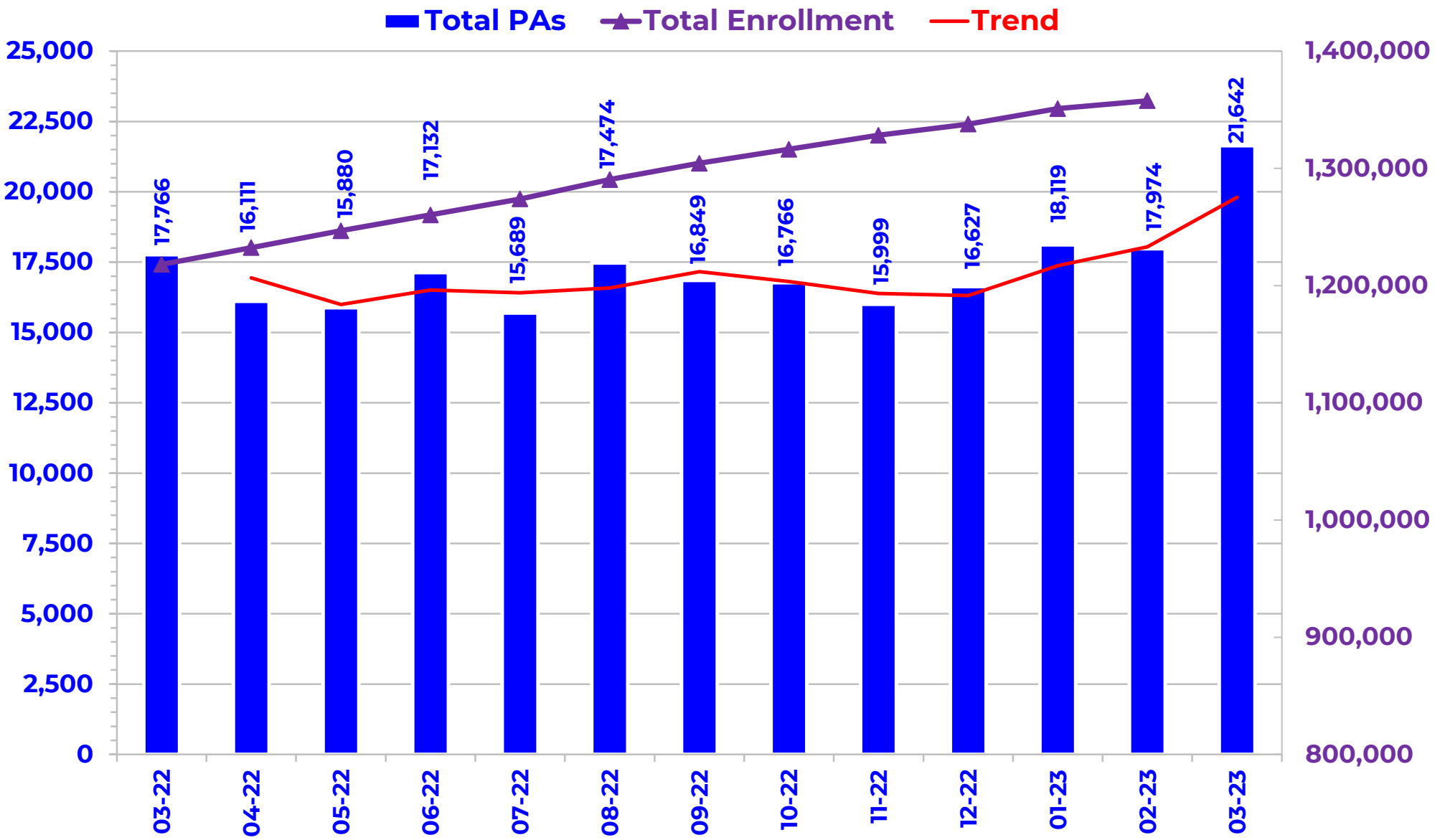
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: MARCH 2023



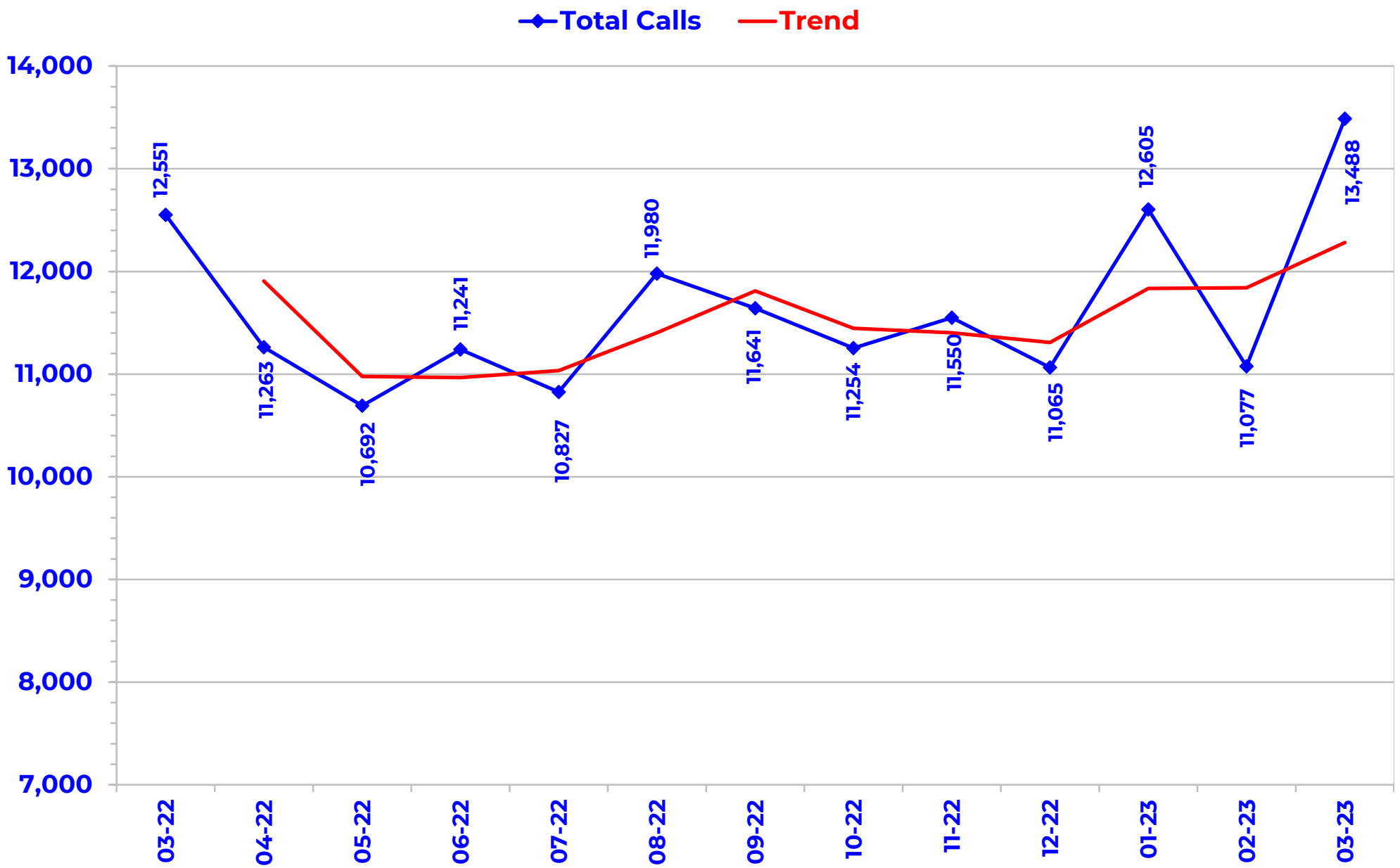
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: MARCH 2022 – MARCH 2023



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: MARCH 2022 – MARCH 2023



Prior Authorization Activity

3/1/2023 Through 3/31/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	144	37	6	101	360
Analgesic - NonNarcotic	17	1	4	12	361
Analgesic, Narcotic	443	197	29	217	133
Angiotensin Receptor Antagonist	13	0	2	11	0
Anti-inflammatory	10	5	0	5	236
Antiasthma	156	46	59	51	246
Antibiotic	63	27	5	31	165
Anticonvulsant	257	127	17	113	324
Antidepressant	472	126	49	297	321
Antidiabetic	3,446	1,160	865	1,421	354
Antifungal	12	4	3	5	129
Antigout	14	6	4	4	309
Antihistamine	81	17	30	34	344
Antimalarial Agent	151	120	2	29	360
Antimigraine	763	150	270	343	240
Antineoplastic	339	238	14	87	171
Antiobesity	55	11	37	7	361
Antiparasitic	40	18	5	17	33
Antiparkinsons	11	1	4	6	361
Antiulcers	71	8	12	51	141
Anxiolytic	49	4	1	44	181
Atypical Antipsychotics	766	326	66	374	355
Benign Prostatic Hypertrophy	17	0	8	9	0
Biologics	491	278	54	159	283
Bladder Control	161	19	54	88	331
Blood Thinners	1,010	651	21	338	345
Botox	104	58	28	18	355
Buprenorphine Medications	136	58	8	70	76
Calcium Channel Blockers	36	5	4	27	360
Cardiovascular	206	96	15	95	330
Chronic Obstructive Pulmonary Disease	428	73	111	244	351
Constipation/Diarrhea Medications	364	71	105	188	216
Contraceptive	49	19	7	23	343
Corticosteroid	17	2	4	11	75
Dermatological	659	212	173	274	216
Diabetic Supplies	1,341	515	245	581	276
Diuretic	13	7	1	5	355
Endocrine & Metabolic Drugs	109	53	16	40	240
Erythropoietin Stimulating Agents	28	18	0	10	101

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Estrogen Derivative	26	5	4	17	360
Fibric Acid Derivatives	17	0	9	8	0
Fibromyalgia	22	4	2	16	350
Fish Oils	30	9	4	17	360
Gastrointestinal Agents	297	64	60	173	187
Genitourinary Agents	13	3	1	9	277
Glaucoma	33	4	6	23	178
Growth Hormones	133	94	18	21	155
Hematopoietic Agents	30	12	4	14	150
Hepatitis C	28	14	1	13	10
HFA Rescue Inhalers	19	2	1	16	361
Insomnia	174	11	46	117	210
Insulin	368	126	38	204	355
Miscellaneous Antibiotics	51	19	1	31	20
Multiple Sclerosis	95	52	4	39	255
Muscle Relaxant	104	10	22	72	208
Nasal Allergy	49	1	14	34	361
Neurological Agents	242	64	54	124	215
Neuromuscular Agents	15	11	2	2	306
Nsaids	57	3	13	41	270
Ocular Allergy	42	7	9	26	202
Ophthalmic	41	10	12	19	360
Ophthalmic Anti-infectives	27	7	0	20	10
Ophthalmic Corticosteroid	32	8	2	22	50
Osteoporosis	56	23	7	26	359
Other*	423	138	57	228	269
Otic Antibiotic	47	5	7	35	153
Pediculicide	19	1	4	14	26
Respiratory Agents	61	41	4	16	339
Statins	80	18	26	36	134
Stimulant	2,823	1,992	116	715	344
Testosterone	226	58	58	110	342
Thyroid	47	13	5	29	322
Topical Antifungal	74	2	26	46	54
Topical Corticosteroids	51	3	17	31	157
Vitamin	183	47	106	30	130
Pharmacotherapy	72	65	1	6	302
Emergency PAs	0	0	0	0	
Total	**18,649**	**7,710**	**3,099**	**7,840**	

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	113	84	4	25	119
Compound	10	9	0	1	26
Cumulative Early Refill	5	5	0	0	7
Diabetic Supplies	1	0	1	0	0
Dosage Change	516	484	3	29	16
High Dose	10	7	0	3	229
IHS-Brand	1	1	0	0	361
Ingredient Duplication	2	2	0	0	16
Lost/Broken Rx	160	145	5	10	18
MAT Override	346	298	4	44	85
NDC vs Age	374	265	42	67	284
NDC vs Sex	22	18	0	4	158
Nursing Home Issue	62	57	0	5	14
Opioid MME Limit	96	41	4	51	135
Opioid Quantity	38	29	1	8	174
Other	76	58	12	6	26
Quantity vs Days Supply	1,011	720	42	249	246
STBS/STBSM	16	14	2	0	141
Step Therapy Exception	18	7	3	8	360
Stolen	22	17	0	5	31
Third Brand Request	94	64	0	30	18
Overrides Total	**2,993**	**2,325**	**123**	**545**	
Total Regular PAs + Overrides	**21,642**	**10,035**	**3,222**	**8,385**	

Denial Reasons	
Unable to verify required trials.	7,278
Does not meet established criteria.	3,279
Lack required information to process request.	1,208
Other PA Activity	
Duplicate Requests	2,267
Letters	46,729
No Process	3
Changes to existing PAs	1,906
Helpdesk Initiated Prior Authorizations	1,428
PAs Missing Information	3,002

* Includes any therapeutic category with less than 10 prior authorizations for the month.

SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

Oklahoma Health Care Authority
April 2023

SoonerPsych Prescriber Mailing Summary

The SoonerPsych program is an educational quarterly mailing to prescribers of atypical antipsychotic medications. Each mailing includes a gauge showing prescribers how their prescribing compares to other SoonerCare prescribers of these medications and how their prescribing potentially differs from evidence-based recommendations. Each mailing also includes an informational page with evidence-based material related to the mailing topics. Mailing topics are comprised of 4 modules: adherence, diagnosis, metabolic monitoring, and polypharmacy as defined below.

The SoonerPsych program has been using a "report card" format since April 2014. Beginning in April 2016, educational letters were sent to the same cohort of prescribers with all modules included in each mailing. The mailing cohort list is updated approximately every 2 years, and cohort prescribers receive 4 letters per year to more completely summarize their SoonerCare members taking these medications and to more conveniently follow changes and improvements in their patients and prescribing patterns over time. The mailing list was last updated in January 2022, and inclusion criteria required the prescriber to have at least 4 SoonerCare members taking atypical antipsychotic medications.

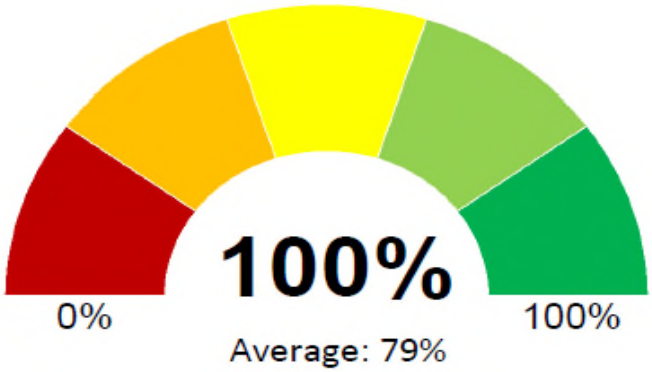
Effective January 2017, data collection was expanded from a previous research-based approach to include additional diagnosis fields and monitoring fields (lipids and glucose) in order to provide a more clinically meaningful description for prescribers. The following list outlines definitions for each module included in the revised SoonerPsych mailing:

- **Adherence:** Adherence is defined as members whose proportion of days covered (PDC) or adherence calculated from pharmacy claims history for atypical antipsychotic medications was ≥80%.
- **Diagnosis:** Diagnosis is defined as members whose recent 12-month medical claims history included a diagnosis with a strong indication for prescribing an atypical antipsychotic medication. These diagnoses include: schizophrenia, bipolar disorder, delusional disorders, other nonorganic psychoses, autism spectrum disorder, mood disorder, obsessive-compulsive disorder, and severe depression with or without psychotic features.

- **Metabolic Monitoring:** Metabolic monitoring is defined as members whose recent 12-month medical claims history included glucose testing. Metabolic monitoring also evaluates the recent 12-month medical claims history for lipid testing for members with a diagnosis of hyperlipidemia.
- **Polypharmacy:** Polypharmacy is defined as members whose pharmacy claims history indicated concurrent use of 2 or more atypical antipsychotic medications for >90 days.

SoonerPsych Example Gauge

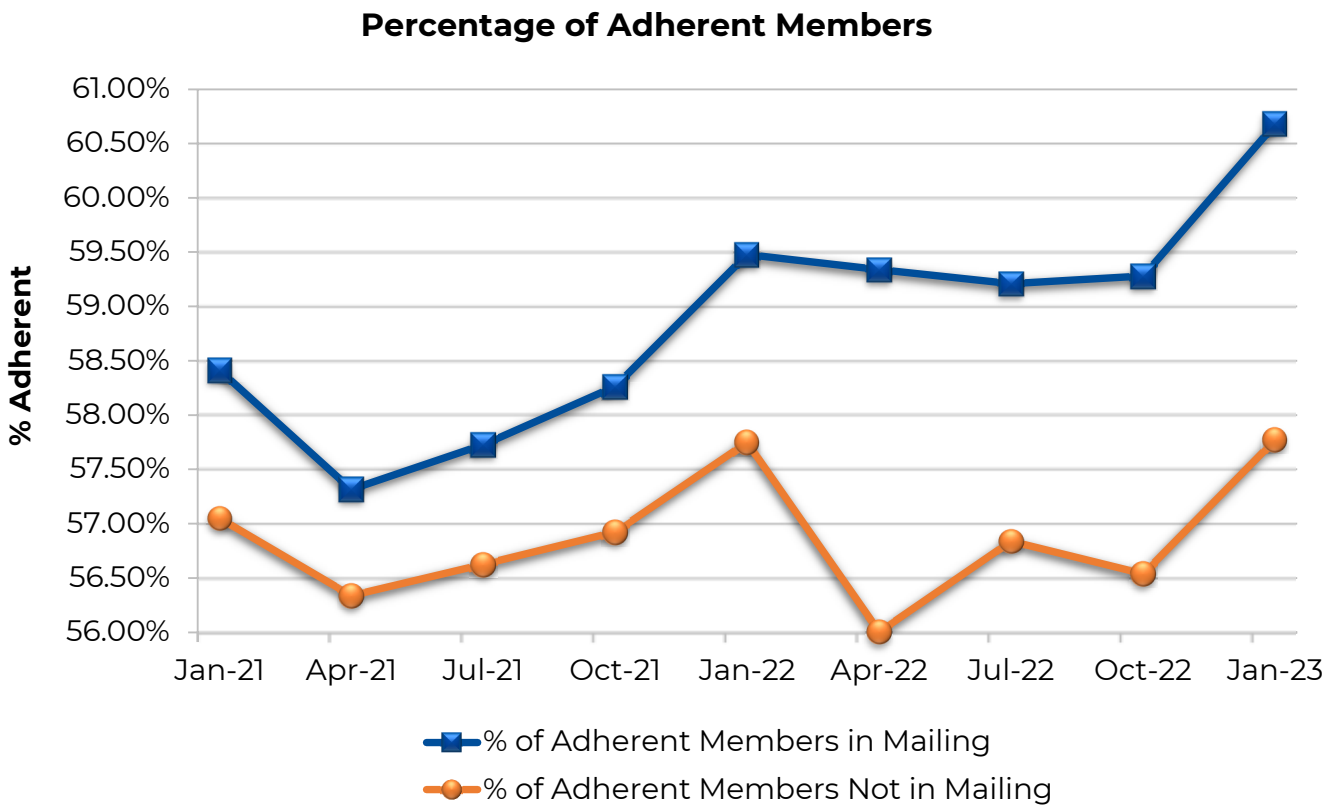
Each gauge includes the individual prescriber's performance in relation to the specific module as well as the average of other SoonerCare prescribers for comparison. The following is an example gauge included in the mailings.



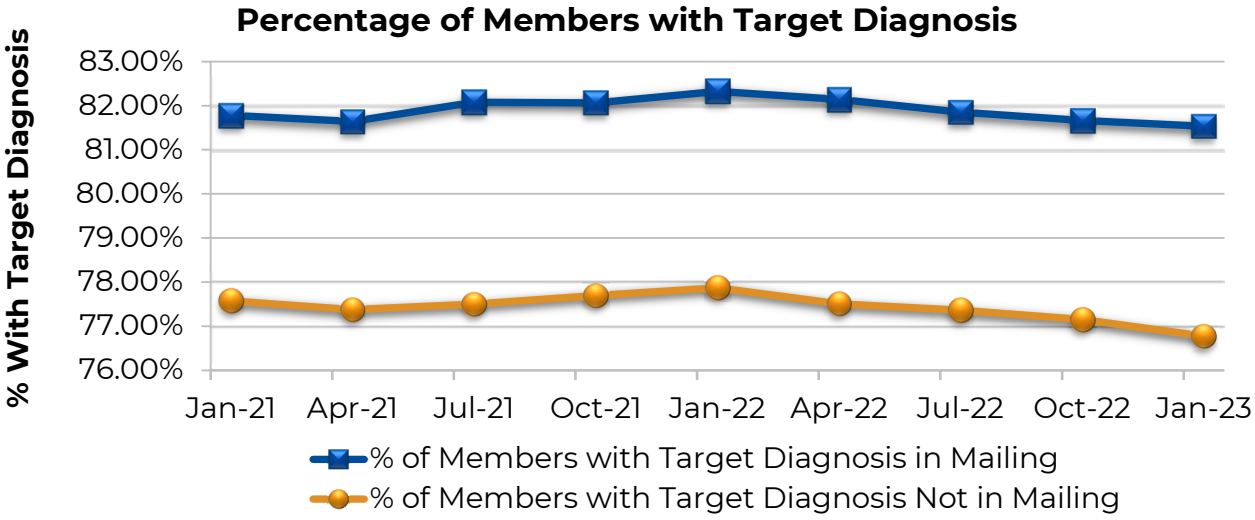
SoonerPsych Trends

The following graphs show the SoonerPsych trends for member adherence, diagnosis, metabolic monitoring, and polypharmacy from January 2021 to January 2023. Members whose prescribers were included in the SoonerPsych mailings are designated separately from those members whose prescribers were not included in the mailings. It is important to note that starting with the July 2019 mailing, the SoonerPsych data was adjusted for outliers, after input from the Drug Utilization Review (DUR) Board at the July 2019 DUR Board meeting, to show a more meaningful comparison of prescribers included in the mailing and prescribers not included in the mailing. Although SoonerPsych trends are tracked over time, it may be more meaningful to evaluate the mailings starting in January 2022 and going forward as a new data set since the prescriber mailing list was last updated in January 2022 to include a larger number of prescribers and prescribers who were not previously receiving a mailing.

The following graph shows the SoonerPsych trends for the percentage of adherent members. Members are considered adherent if their PDC was ≥80%. Please note, the vertical axis starts at 56% of members in order to reflect small changes.

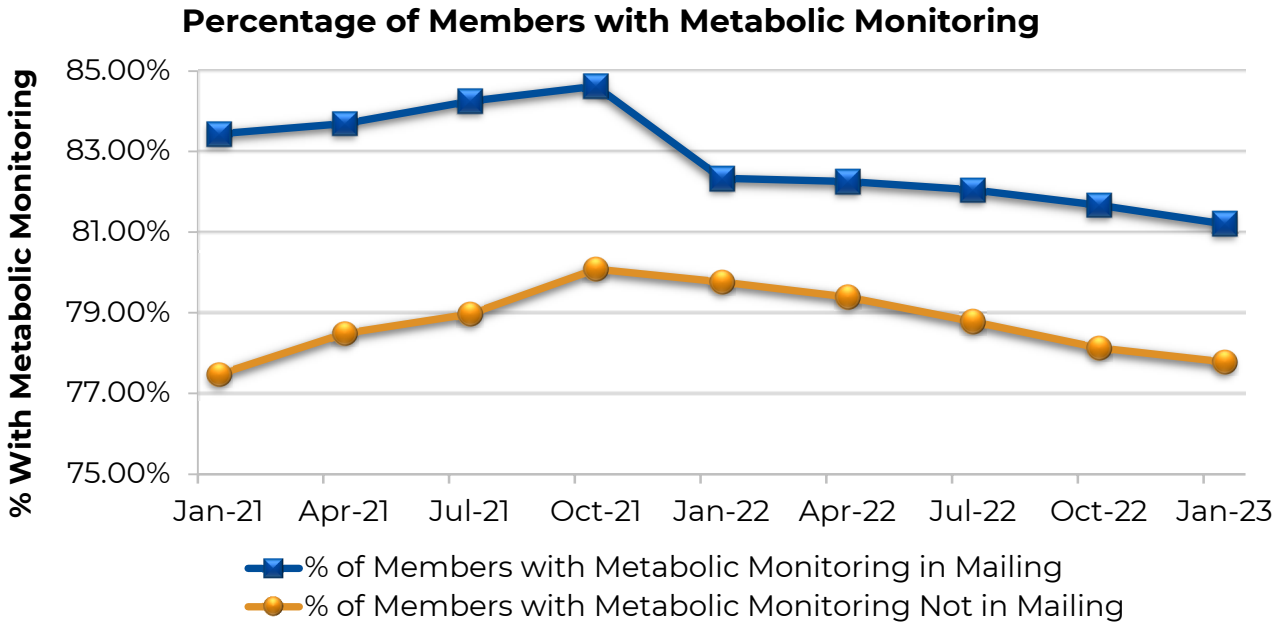


The following graph shows the SoonerPsych trends for the percentage of members whose recent 12-month medical claims history included a diagnosis with a strong indication for prescribing an antipsychotic medication. Please note, the vertical axis starts at 76% of members in order to reflect small changes.

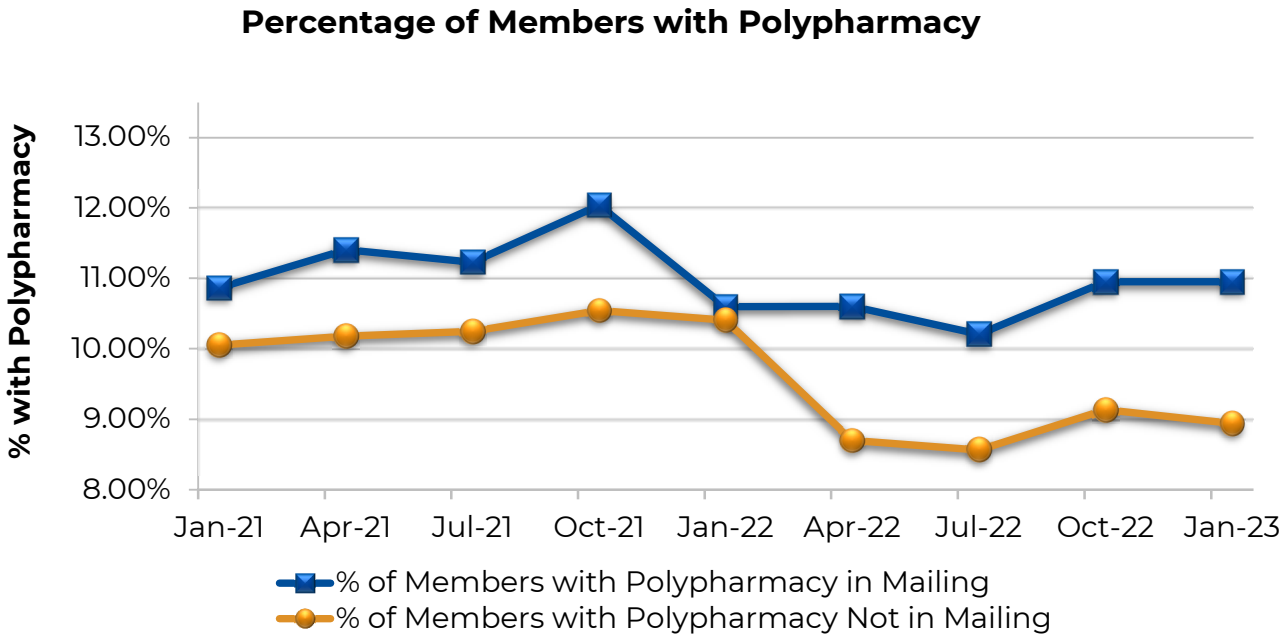


The following graph shows the SoonerPsych trends for the percentage of members with appropriate metabolic monitoring while on an antipsychotic

medication. Please note, the vertical axis starts at 75% of members in order to reflect small changes.



The following graph shows the SoonerPsych trends for the percentage of members with polypharmacy (concurrent use of 2 or more atypical antipsychotic medications for >90 days). Please note, the vertical axis starts at 8.0% of members in order to reflect small changes, and a lower percentage is a better outcome (indicates less prescribing of concomitant atypical antipsychotic medications).



Pediatric SoonerPsych Antipsychotic Monitoring Program Prescriber Mailing Summary

The Oklahoma Health Care Authority (OHCA) is also responsible for establishing and maintaining an additional program to monitor and manage appropriate utilization of antipsychotic medications specifically for children, including children in the foster care system, as part of a requirement by the Centers for Medicare and Medicaid Services (CMS). To accomplish these purposes, the College of Pharmacy developed the Pediatric SoonerPsych program in October 2019. Pediatric SoonerPsych is updated twice per year and includes providers caring for pediatric members receiving antipsychotic medications. Specific provider focus alternates on a semi-annual basis between all children and those children in the foster care system. Pediatric SoonerPsych evaluates prescribing patterns and medical claims across 4 topics as previously described: medication adherence, target diagnosis, polypharmacy, and metabolic monitoring.

Pediatric SoonerPsych inclusion criteria was limited to providers whose prescribing of antipsychotic medications for pediatric SoonerCare members varied significantly when compared to other SoonerCare providers in 1 or more of the 4 topics listed above.

Providers received an educational mailing and member list if they were the last prescriber of record for an antipsychotic medication and were in the most concerning cohort of prescribers. Following receipt of the Pediatric SoonerPsych mailings, providers were offered a virtual or in-person visit by an academic detailing pharmacist and/or a consultation with an OHCA child psychiatrist. Providers were encouraged to participate in the pediatric psychiatry Project ECHO (Extension for Community Health Care Outcomes) for medical education and care management. Additional services through OHCA Care Management and Behavioral Health Care Management were also encouraged. Providers meeting criteria for pediatric members receive mailings and educational offerings each December. Providers meeting criteria for pediatric members in the foster care system receive mailings and educational offerings each June.

Pediatric SoonerPsych Trends

The following tables show the resultant changes observed from 12/1/2021 through 11/30/2022. Provider numbers have been assigned to preserve the privacy of providers and will change as new providers are included in recent cohorts. In all tables, a lower number indicates improvement. Historically, improvement in the area of adherence has proved difficult to measure. Medication adherence appeared to improve from 161 total members to 153 members with PDC <80%. The Pediatric SoonerPsych educational materials emphasize the appropriate use of antipsychotic medications for appropriate

diagnoses. Lowering the dose and/or frequency (i.e., tapering) of these medications with eventual discontinuation is suggested for members who do not meet diagnostic criteria. With this in mind, some intentional medication tapering may be represented as poor adherence.

Across all topics, at least 1 provider was able to improve to the degree that they no longer met criteria for the next mailing's cohort. Additionally, modest summative improvement was seen across all categories, with the exception of polypharmacy.

The following table shows the number of pediatric members having poor adherence (PDC <80%) to antipsychotic medication(s) for each cohort provider.

Pediatric SoonerPsych Trends: Poor Adherence (PDC <80%)		
Provider #	**2021 Number of Members**	**2022 Number of Members**
27	*	10
32	*	28
36	63	47
41	21	*
42	10	*
47	*	46
52	39	*
73	28	22
Total◊	**161**	**153**

*Did not meet cohort criteria
◊ Lower number indicates improvement
PDC = proportion of days covered

The following table shows the number of pediatric members without a diagnosis supporting the use of antipsychotic medications for each cohort provider. There was a 25% decrease in the number of pediatric members without an appropriate diagnosis for the most concerning cohort of prescribers, representing the largest improvement in this topic to date.

Pediatric SoonerPsych Trends: Lack of Target Diagnosis		
Provider #	**2021 Number of Members**	**2022 Number of Members**
15	31	*
28	*	28
31	*	15
36	51	62
52	76	*
54	*	11
55	11	*
60	18	23
Total◊	**187**	**139**

*Did not meet cohort criteria
◊ Lower number indicates improvement

The following table shows the number of members receiving 2 or more antipsychotic medications for >90 days for each cohort provider.

Pediatric SoonerPsych Trends: Polypharmacy		
Provider #	**2021 Number of Members**	**2022 Number of Members**
15	*	6
19	5	*
31	*	4
35	*	4
36	5	*
41	6	6
53	14	16
65	5	*
Total◊	**35**	**36**

*Did not meet cohort criteria
◊ Lower number indicates improvement

The following table shows the number of pediatric members receiving antipsychotic medication(s) with no metabolic monitoring for each cohort provider.

Pediatric SoonerPsych Trends: Lack of Metabolic Monitoring		
Provider #	**2021 Number of Members**	**2022 Number of Members**
5	1	*
13	3	*
24	*	1
49	1	*
50	1	*
63	*	1
67	1	*
Total◊	**7**	**2**

*Did not meet cohort criteria
◊ Lower number indicates improvement

Conclusions

Recent SoonerPsych trends comparing January 2021 through January 2023 indicate overall improvements in the percentage of adherent members, the percentage of members with a target diagnosis, and the percentage of members with metabolic monitoring. The percentage of members with polypharmacy is similar for members whose prescribers received the SoonerPsych mailings compared to those not included in the mailings in 2021 and 2022. Polypharmacy previously did not show positive trends in 2019 for those prescribers included in the mailing; however, after adjusting the data for outliers starting in July 2019, the percentage of members with polypharmacy was similar for members whose prescribers received the mailings compared to those not included in the mailings. Continuing to adjust the data for outliers and following the results of the new prescriber list over time may provide more opportunities for additional prescriber-specific interventions. Overall, results indicate consistently receiving evidence-based educational mailings reminds prescribers of evidence-based practices and reduces some potentially inappropriate prescribing. Recent changes to the mailing format (including all modules in each mailing, mailing to consistent prescribers, and updating the prescriber mailing list), as well as expanding the data collection process and adjusting the data for outliers, are intended to sustain improvements and reduce waning interventions. The College of Pharmacy will continue to work with OHCA to improve educational mailings with the goal of improving the quality of care for SoonerCare members utilizing atypical antipsychotic medications.

Since the Pediatric SoonerPsych program initiation, trends indicate overall improvements in the areas of diagnosis, metabolic monitoring, and polypharmacy. Improvements in the area of adherence are more difficult to determine, owing to the likely co-occurrences of true poor adherence and

intentional tapering. The greatest improvements continue to be seen in the area of metabolic monitoring, and more recently, target diagnosis. In the case of metabolic monitoring, only 2 prescribers met the inclusion criteria at the end of the monitoring year. Overall results indicate the Pediatric SoonerPsych focused mailing and educational offerings are likely leading to improvements in antipsychotic medication management resulting in a lower risk of overprescribing and increased rates of recommended metabolic monitoring. The College of Pharmacy will continue to work with OHCA to identify providers who may benefit from Pediatric SoonerPsych activities with the goal of promoting evidence-based use of antipsychotic medications for pediatric members.

Future results of the SoonerPsych and Pediatric SoonerPsych activities will be reviewed with the DUR Board as they become available.

Appendix C

Vote to Prior Authorize Briumvi™ (Ublituximab-xiiy) and Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)] and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications

Oklahoma Health Care Authority
April 2023

Market News and Updates[1,2,3,4]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **December 2022:** The FDA approved Briumvi™ (ublituximab-xiiy) for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), and active secondary progressive disease (SPMS), in adults.
- **January 2023:** The FDA approved a 0.5mg strength of Tascenso ODT®, a bioequivalent ODT formulation of Gilenya® (fingolimod oral capsules). Tascenso ODT® was first approved in December 2021 at a 0.25mg dose for pediatric patients 10 years of age and older who weigh ≤40kg. Tascenso ODT® is approved for the same indications as Gilenya® of RMS, to include CIS, RRMS, and SPMS, in patients 10 years of age and older.

Briumvi™ (Ublituximab-xiiy) Product Summary[5]

Indication(s): Briumvi™ is a CD20-directed cytolytic antibody indicated for the treatment of RMS, to include CIS, RRMS, and active SPMS, in adults.

How Supplied: 150mg/6mL single-dose vial (SDV)

Dosing and Administration:

- Briumvi™ should be administered via intravenous (IV) infusion:
  - 1st infusion: 150mg
  - 2nd infusion: 450mg 2 weeks after the first dose
  - Subsequent infusions: 450mg 24 weeks after the first infusion and every 24 weeks thereafter
- Hepatitis B virus (HBV) screening and quantitative serum immunoglobulin screening should be performed before the first dose.
- Patients should be pre-medicated with methylprednisolone (or an equivalent corticosteroid) and an antihistamine (e.g., diphenhydramine) prior to each infusion.
- Patients should be monitored closely during and for at least 1 hour after the completion of the first 2 infusions. Post-infusion monitoring of

subsequent infusions should be at the discretion of the physician unless an infusion reaction and/or hypersensitivity has been observed.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Year
Aubagio® (teriflunomide) 14mg tablet	$300.99	$108,356.40¥
Kesimpta® (ofatumumab) 20mg/0.4mL Sensoready® Pen	$8,164.09	$106,133.17±
Ocrevus® (ocrelizumab) 300mg/10mL SDV	$1,877.56	$75,102.40*
Briumvi™ (ublituximab-xiiy) 150mg/6mL SDV	**$1,638.89**	**$59,000.04⁺**

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
¥Aubagio® cost per year based on maintenance dose of 14mg once daily.
±Kesimpta® cost per year based on maintenance dose of 20mg every 4 weeks.
*Ocrevus® cost per year based on maintenance dose of 600mg every 6 months.
⁺Briumvi™ cost per year based on maintenance dose of 450mg every 24 weeks.
SDV = single-dose vial; Unit = each tablet for Aubagio®, each pen for Kesimpta®, and each mL for Ocrevus® and Briumvi™

Cost Comparison: Fingolimod Products

Medication	Cost Per Unit	Cost Per Month	Cost Per Year*
Tascenso ODT® (fingolimod) 0.5mg ODT	**$347.43**	**$10,422.90**	**$125,074.80**
Gilenya® (fingolimod) 0.5mg capsule	$337.92	$10,137.60	$121,651.20
generic fingolimod 0.5mg capsule	$74.03⁺	$2,220.90	$26,650.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per year based on maintenance dose of 0.5mg once daily
⁺Cost per capsule varies per NDC.
ODT = orally disintegrating tablet; Unit = capsule or ODT

Recommendations

The College of Pharmacy recommends the prior authorization of Briumvi™ (ublituximab-xiiy) and Tascenso ODT® (fingolimod ODT) with the following criteria (shown in red):

Briumvi™ (Ublituximab-xiiy) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have had at least 1 relapse in the previous 12 months; and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Briumvi™ must be administered by a health care professional in a setting with appropriate equipment and personnel to manage

anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Briumvi™ will be administered; and
   a. Briumvi™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
   b. Briumvi™ must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Briumvi™; and
6. Prescriber must confirm that member will be monitored for 1 hour following the first 2 infusions and as indicated for subsequent infusions; and
7. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating Briumvi™ therapy and member does not have active HBV; and
8. Verification from the prescriber that member has no active infection(s); and
9. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving Briumvi™ therapy and for 6 months after the last infusion of Briumvi™; and
10. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have had at least 1 relapse in the previous 12 months; and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Prescriber must confirm that member will be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
6. Verification from the prescriber that member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. A patient-specific, clinically significant reason why the member cannot use Gilenya® (fingolimod) capsules must be provided; and

10. Compliance will be checked for continued approval every 6 months.

Additionally, the College of Pharmacy recommends updating the Ocrevus® (ocrelizumab) approval criteria to address the safe and proper administration of the medication and to be consistent with the approval criteria for Briumvi™ (ublituximab-xiiy) (changes shown in red):

Ocrevus® (Ocrelizumab) Approval Criteria:

1. An FDA approved diagnosis of primary progressive forms of multiple sclerosis (MS) or relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease modifying therapies; and
4. ~~Ocrevus® must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. The prescriber must agree that the member will be monitored for 1 hour after each infusion; and~~
5. Ocrevus® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Ocrevus® will be administered; and
    a. Ocrevus® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Ocrevus® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Ocrevus®; and
6. Prescriber must confirm that member will be monitored for 1 hour after each infusion; and
7. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating Ocrevus® therapy and member does not have active HBV; and
8. Verification from the prescriber that member has no active infection(s); and
9. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving Ocrevus® therapy and for 6 months after the last infusion of Ocrevus®; and
10. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

The College of Pharmacy also recommends updating the Mavenclad® (cladribine) approval criteria to be consistent with the package labeling regarding duration of use (changes shown in red):

Mavenclad® (Cladribine) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults; and
2. Requests for use in patients with clinically isolated syndrome (CIS) will not generally be approved; and
3. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
4. Member must have had at least 1 relapse in the previous 12 months; and
5. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
6. Prescriber must confirm that the member does not have any contraindications for use of cladribine; and
7. Prescriber must confirm member does not have an active malignancy; and
8. Prescriber must confirm that female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
9. Prescriber must attest that female and male members of reproductive potential plan to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; and
10. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
11. Verification from the prescriber that member has no active infection(s); and
12. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
13. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
14. Quantity limits according to package labeling will apply; and
15. Approvals will be for 1 year of therapy (1 treatment course/2 cycles) at a time. Lifetime approval duration will be limited to a maximum of 2 treatment courses according to package labeling.

Finally, the College of Pharmacy recommends the following changes to the MS medications approval criteria to be consistent with clinical practice (changes shown in red):

Multiple Sclerosis Interferon Medications	
Tier-1	**Tier-2**
interferon β - 1a (Avonex®)	interferon β - 1a (Rebif®)
interferon β - 1b (Betaseron®)	interferon β - 1b (Extavia®)
peginterferon β - 1a (Plegridy®)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Multiple Sclerosis (MS) Interferon Medications Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of MS, or secondary progressive forms of MS; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Authorization of Tier-2 medications requires previous failure of preferred Tier-1 medication(s) defined as:
   a. Occurrence of an exacerbation after 6 months; or
   b. Significant increase in magnetic resonance imaging (MRI) lesion after 6 months; or
   c. Adverse reactions or intolerable side effects; and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Compliance will be checked for continued approval every 6 months.

Ampyra® (Dalfampridine) Approval Criteria:

1. An FDA approved indication to improve walking in adult members with multiple sclerosis (MS); and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Kurtzke Expanded Disability Status Scale (EDSS) score between 3 and 7.5; and
4. Initial approvals will be for the duration of 90 days. If the member has responded well to treatment and the prescriber states that the member has shown improvement or the drug was effective, the member may receive authorization for 1 year; and
5. A quantity limit of 60 tablets for 30 days will apply.
6. Ampyra® may be used with other MS therapies.

Aubagio® (Teriflunomide) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and

4. Brand name Aubagio® is preferred. Use of generic teriflunomide will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. All of the following will be required for initiation of treatment:
    a. Verification that female members are not pregnant and are currently using reliable contraception; and
    b. Verification that the member has no active infection(s); and
    c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
    d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
    e. Blood pressure (BP) measurement and verification that BP is being monitored; and
    f. Verification that the member does not have tuberculosis (TB), or completion of standard medical treatment for members with TB; and
6. Initial approvals of Aubagio® will be for 6 months, after which time all of the following will be required for further approval:
    a. Medication compliance; and
    b. Repeat CBC and verification that counts are acceptable to the prescriber; and
    c. Repeat LFTs and verification that levels are acceptable to the prescriber; and
    d. Verification that female members are not pregnant and will continue using reliable contraception; and
    e. Verification that BP and signs of renal failure are being monitored; and
7. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 30 tablets per 30 days will apply.

Bafiertam® (Monomethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no serious active infection(s); and
5. Complete blood counts (CBC), including lymphocyte count, and verification that levels are acceptable to the prescriber; and

6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Intolerable adverse effects associated with a trial of Tecfidera® (dimethyl fumarate) and Vumerity® (diroximel fumarate) that are not expected to occur with Bafiertam® or a patient-specific, clinically significant reason why trials of Tecfidera® and Vumerity® are not appropriate for the member must be provided; and
8. Verification that CBC, including lymphocyte count, levels are acceptable to the prescriber in addition to compliance will be required for continued approval every 6 months; and
9. A quantity limit of 4 capsules per day will apply.

Copaxone® (Glatiramer Acetate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Approvals for the 40mg strength of Copaxone® will require a patient-specific, clinically significant reason why the member cannot use the 20mg strength; and
5. Approvals for the generic formulation of either strength of Copaxone®, including Glatopa®, will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
6. Compliance will be checked for continued approval every 6 months.

Gilenya® (Fingolimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS)*, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
   (*The manufacturer of Gilenya® has provided a supplemental rebate to remove the requirement of “at least 1 relapse in the previous 12 months, or transitioning from existing MS therapy”; however, Gilenya® will follow the original criteria if the manufacturer chooses not to participate in supplemental rebates); and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and

4. Prescriber must confirm that member will ~~The first dose should~~ be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
5. Verification from the prescriber that member has no active infection(s); and
6. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
7. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
8. Compliance will be checked for continued approval every 6 months.

Kesimpta® (Ofatumumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have had at least 1 relapse in the previous 12 months; and
4. The prescriber must verify Hepatitis B virus (HBV) screening is performed before the first dose of Kesimpta® and the member does not have an active HBV infection; and
5. Prescriber must agree to monitor quantitative serum immunoglobulin level before, during, and after discontinuation of treatment with Kesimpta® until B-cell repletion; and
6. Prescriber must verify the member has no active infection(s); and
7. Prescriber must verify the first injection of Kesimpta® will be administered by a health care professional prepared to manage injection-related adverse reactions; and
8. Kesimpta® must be shipped via cold chain supply and the member or member's caregiver must be trained on the proper storage and subcutaneous (sub-Q) administration of Kesimpta®; and
9. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of treatment with Kesimpta®; and
10. Female members of reproductive potential must use an effective method of contraception during treatment and for 6 months after stopping Kesimpta®; and
11. A quantity limit of 1 syringe or prefilled Sensoready® Pen per month will apply. Initial dosing titration will be approved for a quantity limit override upon meeting Kesimpta® approval criteria; and
12. Compliance will be checked for continued approval every 6 months.

Lemtrada® (Alemtuzumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
    a. Lemtrada® must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. The prescriber must agree that the member will be monitored for 2 hours after each infusion; and
4. The prescriber must agree to monitor complete blood counts (CBC) with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of Lemtrada®; and
5. The prescriber must agree that baseline and yearly skin examinations will be performed while the member is utilizing Lemtrada® therapy; and
6. Member, prescriber, pharmacy, and health care facility must all enroll in the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program and maintain enrollment throughout therapy.

Mayzent® (Siponimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have been assessed for CYP2C9 genotype:
    a. Members with a CYP2C9*3/*3 genotype will not generally be approved; or
    b. Members with a CYP2C9*1/*3 or *2/*3 genotype will not be approved for doses exceeding 1mg per day; or
    c. All other genotypes CYP2C9 *1/*1, *1/*2, or *2/*2 will be approved for 2mg per day; and
4. Member must not have any contraindication for use of siponimod including:
    a. CYP2C9*3/*3 genotype; or
    b. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or Class III/IV HF in the last 6 months; or

    c. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and
5. Member must not have received prior treatment with alemtuzumab; and
6. Verification from the prescriber that member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
10. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate (HR) or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and
11. Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without history of chickenpox or varicella vaccination should receive a full course of varicella vaccine prior to commencing treatment with Mayzent®; and
12. Verification from the prescriber that members with sinus bradycardia (HR <55 beats per minute), first- or second-degree AV block (Mobitz type I), or a history of HF or MI will be monitored following the first dose for a minimum of 6 hours; and
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
14. Female members of reproductive potential must be willing to use effective contraception during treatment with Mayzent® and for at least 10 days after discontinuing treatment; and
15. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
16. Compliance will be checked for continued approval every 6 months; and
17. Quantity limits according to package labeling will apply.

Ponvory® (Ponesimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and

3. Member must not have any contraindications for use of Ponvory® including:
    a. Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or
    b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and
4. Member must not have received prior treatment with alemtuzumab; and
5. Member must not be concurrently using strong CYP3A4 and UGT1A1 inducers (e.g., rifampin, phenytoin, carbamazepine); and
6. Verification from the prescriber that the member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Verification from the prescriber that the member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Ponvory®; and
9. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
10. Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and
11. Verification from the prescriber that the member has undergone an ophthalmic evaluation prior to starting therapy with Ponvory® and the member will be monitored for changes in vision throughout therapy; and
12. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring per package labeling; and
13. Verification from the prescriber that the member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Ponvory®; and
14. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
15. Female members of reproductive potential must be willing to use effective contraception during treatment with Ponvory® and for at least 1 week after discontinuing treatment; and
16. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and

17. Compliance will be checked for continued approval every 6 months; and
18. A quantity limit of 30 tablets per 30 days will apply for the 20mg tablet. A quantity limit of 14 tablets per 14 days will apply for the Ponvory® starter pack.

Tecfidera® (Dimethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of multiple sclerosis (MS), or secondary progressive forms of MS in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no active infection(s); and
5. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 60 tablets per 30 days will apply.

Vumerity® (Diroximel Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no serious active infection(s); and
5. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Verification from the prescriber that member does not have moderate or severe renal impairment; and
8. Verification from the prescriber that the member has been counseled on proper administration of Vumerity® including caloric and fat intake limits at the time of dosing; and

9. Compliance will be checked for continued approval every 6 months; and
10. A quantity limit of 120 capsules per 30 days will apply.

Zeposia® (Ozanimod) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following in adults:
    a. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; or
    b. Moderately to severely active ulcerative colitis (UC); and
2. For the diagnosis of MS, prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must not have any contraindications for use of Zeposia® including:
    a. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or
    b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; or
    c. Have severe untreated sleep apnea; or
    d. Concurrent use of monoamine oxidase inhibitors (MAOIs); and
4. Member must not have received prior treatment with alemtuzumab; and
5. Member must not be concurrently using strong CYP2C8 inhibitors/ inducers or breast cancer resistance protein (BCRP) inhibitors; and
6. Verification from the prescriber that member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Prescriber must conduct an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Zeposia®; and
9. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
10. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
11. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and

12. Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
14. Female members of reproductive potential must be willing to use effective contraception during treatment with Zeposia® and for at least 3 months after discontinuing treatment; and
15. For the diagnosis of MS, member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; or
16. For the diagnosis of UC, member must have had an inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators (e.g., 6-mercaptopurine, azathioprine), and a biologic [e.g., tumor necrosis factor (TNF) blocker]. Tier structure applies; and
17. Compliance will be checked for continued approval every 6 months; and
18. A quantity limit of 30 capsules per 30 days will apply.

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[1] TG Therapeutics. TG Therapeutics Announces FDA Approval of Briumvi™ (Ublituximab-xiiy). Available online at: https://ir.tgtherapeutics.com/news-releases/news-release-details/tg-therapeutics-announces-fda-approval-briumvitm-ublituximab. Issued 12/28/2022. Last accessed 03/24/2023.
[2] Roy S, Mandowara K. FDA Approves TG Therapeutics' Multiple Sclerosis Drug; Shares Surge. *Medscape*. Available online at: https://www.medscape.com/viewarticle/986262. Issued 12/29/2022. Last accessed 03/24/2023.
[3] Shapiro L. Tascenso ODT®, a Gilenya® Alternative, Wins New FDA Approval in MS. *Multiple Sclerosis News Today*. Available online at: https://multiplesclerosisnewstoday.com/news-posts/2023/01/19/tascenso-odt-gilenya-bioequivalent-wins-fda-approval-ms/. Issued 01/19/2023. Last accessed 03/24/2023.
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[5] Briumvi™ (Ublituximab-xiiy) Prescribing Information. TG Therapeutics. Available online at: https://www.tgtherapeutics.com/label-prescribing-info/uspi-briumvi.pdf. Last revised 12/2022. Last accessed 03/24/2023.

Appendix D

Vote to Prior Authorize Lamzede® (Velmanase Alfa-tycv)

Oklahoma Health Care Authority
April 2023

Market News and Updates[1,2,3,4]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **February 2023:** The FDA approved Lamzede® (velmanase alfa-tycv) for the treatment of non-central nervous system (CNS) manifestations of alpha-mannosidosis in adult and pediatric patients. Lamzede® is the first and only enzyme replacement therapy FDA approved for this indication. Alpha-mannosidosis is a rare, genetic, lysosomal storage disorder characterized by a deficiency of alpha-mannosidase, an enzyme responsible for catalyzing the degradation of mannose-containing oligosaccharides and glycoproteins. Alpha-mannosidosis is caused by mutations in the *MAN2B1* gene and is inherited in an autosomal recessive manner. In patients with alpha-mannosidosis, low levels or inactivity of the alpha-mannosidase enzyme cause a toxic accumulation of mannose-containing oligosaccharides in cells, leading to damage in various tissues and organs throughout the body. The symptoms and severity of alpha-mannosidosis vary greatly between patients, but symptoms frequently include distinctive coarse facial features, skeletal abnormalities, hearing loss, frequent infections, developmental delay, intellectual disability, and ataxia. Some patients also experience psychiatric symptoms, hepatosplenomegaly, cataracts, or other ocular changes.

Lamzede® (Velmanase Alfa-tycv) Product Summary[5]

Indication(s): Lamzede® is a recombinant human lysosomal alpha-mannosidase indicated for treatment of non-CNS manifestations of alpha-mannosidosis in adult and pediatric patients.

How Supplied: 10mg lyophilized powder in a single-dose vial (SDV) for reconstitution

Dosing and Administration:

- The recommended dose is 1mg/kg (actual body weight) administered once weekly as an intravenous (IV) infusion.
- Prior to initiating treatment, pregnancy status should be verified, and females of reproductive potential should not be pregnant.

- Pretreatment with antihistamines, antipyretics, and/or corticosteroids should be considered.
- Refer to the full *Prescribing Information* for recommended dosage and administration modifications due to hypersensitivity and/or infusion-related reactions.

Cost: The Wholesale Acquisition Cost (WAC) of Lamzede® is $4,000 per 10mg SDV. This results in an estimated cost of $112,000 per 28 days and $1,456,000 per year based on the recommended dose of 1mg/kg once weekly for an adult member weighing 70kg.

Recommendations

The College of Pharmacy recommends the prior authorization of Lamzede® (velmanase alfa-tycv) with the following criteria (shown in red):

Lamzede® (Velmanase Alfa-tycv) Approval Criteria:

1. An FDA approved diagnosis of alpha-mannosidosis confirmed by:
   a. Documented lab results verifying alpha-mannosidase activity <11% of normal; or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *MAN2B1* gene; and
2. Member's recent weight (kg) taken within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
3. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Lamzede®; and
4. Lamzede® must be administered in a health care setting by a health care provider with appropriate equipment and personnel to manage anaphylaxis. Approvals will not be granted for self-administration; and
   a. Lamzede® must be shipped via cold chain supply to the health care setting where the member is scheduled to receive treatment; and
5. Lamzede® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; and
6. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents the member is responding well to treatment.

[1] National Organization for Rare Disorders (NORD). Alpha-Mannosidosis. Available online at: https://rarediseases.org/rare-diseases/alpha-mannosidosis/. Last revised 08/13/2018. Last accessed 03/21/2023.
[2] Malm D, Nilssen O. Alpha-Mannosidosis. *GeneReviews*®. Available online at: https://www.ncbi.nlm.nih.gov/books/NBK1396/. Last revised 07/18/2019. Last accessed 03/21/2023.
[3] Genetic and Rare Diseases (GARD) Information Center. Alpha-Mannosidosis. Available online at: https://rarediseases.info.nih.gov/diseases/6968/alpha-mannosidosis. Last revised 02/2023. Last accessed 03/21/2023.
[4] Chiesi Global Rare Diseases. Chiesi Global Rare Diseases Announces FDA Approval of Lamzede® (Velmanase Alfa-tycv) for Alpha-Mannosidosis. Available online at: https://www.prnewswire.com/news-releases/chiesi-global-rare-diseases-announces-fda-approval-of-lamzedevelmanase-alfa-tycv-for-alpha-mannosidosis-301749440.html. Issued 02/16/2023. Last accessed 03/21/2023.
[5] Lamzede® (Velmanase alfa-tycv) Prescribing Information. Chiesi USA, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761278s000lbl.pdf. Last revised 02/2023. Last accessed 03/21/2023.

Appendix E

Vote to Prior Authorize Rolvedon™ (Eflapegrastim-xnst) and Stimufend® (Pegfilgrastim-fpgk) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs)

Oklahoma Health Care Authority
April 2023

Market News and Updates[1,2,3,4,5,6]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **May 2022:** The FDA approved Fylnetra® (pegfilgrastim-pbbk) as a biosimilar to Neulasta® (pegfilgrastim) to treat chemotherapy-induced neutropenia (CIN).
- **September 2022:** The FDA approved Stimufend® (pegfilgrastim-fpgk) as a biosimilar to Neulasta® (pegfilgrastim) to treat CIN.
- **September 2022:** The FDA approved Rolvedon™ (eflapegrastim-xnst) injection to treat CIN. Eflapegrastim-xnst is a long-acting G-CSF with a novel formulation, which consists of a recombinant human G-CSF analog conjugated to a human aglycosylated IgG4 Fc fragment with a short polyethylene glycol linker. Eflapegrastim-xnst has an extended drug half-life due to its size as well as increased uptake in the bone marrow, presumably due to the interaction of the Fc fragment with Fc receptors on the surface of endothelial cells. In clinical studies, eflapegrastim-xnst demonstrated non-inferiority to pegfilgrastim in the mean duration of severe neutropenia and had a similar safety profile to pegfilgrastim.

Cost Comparison

Product	Cost Per Syringe
Neulasta® (pegfilgrastim) injection 6mg/0.6mL	$5,868.42
Rolvedon™ (eflapegrastim-xnst) injection 13.2mg/0.6mL	**$4,500.00**
Stimufend® (pegfilgrastim-fpgk) injection 6mg/0.6mL	**$4,175.00**
Fulphila® (pegfilgrastim-jmdb) injection 6mg/0.6mL	$4,175.00
Udenyca® (pegfilgrastim-cbqv) injection 6mg/0.6mL	$4,175.00
Nyvepria™ (pegfilgrastim-apgf) injection 6mg/0.6mL	$3,925.00
Fylnetra® (pegfilgrastim-pbbk) injection 6mg/0.6mL	$2,500.00
Ziextenzo® (pegfilgrastim-bmez) injection 6mg/0.6mL	$1,079.30

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Recommendations

The College of Pharmacy recommends adding Fylnetra® (pegfilgrastim-pbbk) to the preferred products for the pegfilgrastim products and recommends the prior authorization of Nyvepria™ (pegfilgrastim-apgf), Rolvedon™ (eflapegrastim-xnst), and Stimufend® (pegfilgrastim-fpgk) based on net costs (new criteria and changes shown in red):

Fulphila® (Pegfilgrastim-jmdb), Neulasta® (Pegfilgrastim), Nyvepria™ (Pegfilgrastim-apgf), Stimufend® (Pegfilgrastim-fpgk), and Udenyca® (Pegfilgrastim-cbqv) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fylnetra® (pegfilgrastim-pbbk), Granix® (tbo-filgrastim), Neupogen® (filgrastim), ~~Nyvepria™ (pegfilgrastim-apgf),~~ Zarxio® (filgrastim-sndz), or Ziextenzo® (pegfilgrastim-bmez) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Rolvedon™ (Eflapegrastim-xnst) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fylnetra® (pegfilgrastim-pbbk), Granix® (tbo-filgrastim), Neupogen® (filgrastim), Zarxio® (filgrastim-sndz), or Ziextenzo® (pegfilgrastim-bmez) must be provided.

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[1] Amneal Pharmaceuticals, Inc. Amneal Achieves Third U.S. Biosimilar Approval with Fylnetra® (Pegfilgrastim-pbbk). *Business Wire*. Available online at: https://www.businesswire.com/news/home/20220527005044/en/Amneal-Achieves-Third-U.S.-Biosimilar-Approval-with-FYLNETRA. Issued 05/27/2022. Last accessed 03/17/2023.

[2] Fresenius Kabi. Fresenius Kabi Receives U.S. FDA Approval for Biosimilar Stimufend®. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20220906005876/en/Fresenius-Kabi-Receives-U.S.-FDA-Approval-for-Biosimilar-Stimufend. Issued 09/06/2022. Last accessed 03/17/2023.

[3] Spectrum Pharmaceuticals. Spectrum Pharmaceuticals Receives FDA Approval for Rolvedon™. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20220909005522/en/Spectrum-Pharmaceuticals-Receives-FDA-Approval-for-ROLVEDON. Issued 09/09/2022. Last accessed 03/17/2023.

[4] Cobb P, Moon Y, Mezei K, et al. A Comparison of Eflapegrastim to Pegfilgrastim in the Management of Chemotherapy-induced Neutropenia in Patients with Early-Stage Breast Cancer Undergoing Cytotoxic Chemotherapy (RECOVER): A Phase 3 Study. *Cancer Medicine* 2020; 9:6234–6243. doi: 10.1002/cam4.3227.

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[6] Rolvedon™ (Eflapegrastim-xnst) Prescribing Information. Spectrum Pharmaceuticals, Inc. Available online at: https://www.rolvedon.com/pdf/rolvedon-prescribing-information.pdf. Last revised 09/2022. Last accessed 03/17/2023.

Appendix F

Vote to Prior Authorize Airsupra™ (Albuterol/ Budesonide)

Oklahoma Health Care Authority
April 2023

Market News and Updates[1,2]

U.S. Food and Drug Administration (FDA) Approval(s):

- **January 2023:** The FDA approved Airsupra™ (albuterol/budesonide) inhalation aerosol for patients 18 years and older with asthma for as needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations. It is the first combination product of a short acting beta$_2$ agonist (SABA) and an inhaled corticosteroid (ICS).

News:

- **October 2022:** Teva Pharmaceuticals announced that they have discontinued manufacturing brand name ProAir® (albuterol sulfate) inhalation aerosol.

Airsupra™ (Albuterol/Budesonide) Inhalation Aerosol Product Summary[3]

Indication(s): Airsupra™ is indicated for patients 18 years of age and older with asthma for as needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations.

How Supplied: Pressurized metered dose inhaler (MDI) that delivers albuterol 90mcg and budesonide 80mcg per actuation

Dosing and Administration:

- Recommended dose is 180mcg/160mcg (administered as 2 actuations of albuterol/budesonide 90mcg/80mcg) by oral inhalation as needed for asthma symptoms
- Should not exceed more than 6 doses (12 inhalations) in a 24-hour period
- Inhaler should be primed prior to first use and should be re-primed when inhaler has not been used for >7 days, is dropped, or after cleaning
- Should be discarded 12 months after the foil pouch is opened or when the dose counter displays 0, whichever comes first

Cost: The Wholesale Acquisition Cost of Airsupra™ is not currently available.

Recommendations

The College of Pharmacy recommends the prior authorization of Airsupra™ (albuterol/budesonide) with the following criteria (shown in red):

Airsupra™ (Albuterol/Budesonide) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 18 years of age or older; and
3. Member must be using maintenance therapy per the Global Initiative for Asthma (GINA) guidelines; and
4. A patient-specific, clinically significant reason why the member cannot use a long-acting beta$_2$ agonist (LABA), inhaled corticosteroid (ICS)/LABA combination, or specific individual ICS and short-acting beta$_2$ agonist (SABA) components must be provided; and
5. Initial approvals will be for the duration of 3 months. For continued consideration, prescriber must verify the member has had a positive clinical response to therapy; and
6. Subsequent approvals will be for the duration of 1 year.

[1] U.S. Food and Drug Administration (FDA). FDA Approves Drug Combination Treatment for Adults with Asthma. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-drug-combination-treatment-adults-asthma. Last revised 01/11/2023. Last accessed 03/28/2023.
[2] ProAir® (Albuterol Sulfate) Discontinuation Notice. Teva. Available online at: https://www.proair.com/hfa/. Issued 10/01/2022. Last accessed 03/17/2023.
[3] Airsupra™ (Albuterol/Budesonide) Prescribing Information. AstraZeneca. Available online at: https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/fe598cda-d255-4446-998e-617607f61552/fe598cda-d255-4446-998e-617607f61552_viewable_rendition__v.pdf. Last revised 01/2023. Last accessed 03/17/2023.

Appendix G

Vote to Prior Authorize Olpruva™ (Sodium Phenylbutyrate) and Pheburane® (Sodium Phenylbutyrate) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications

Oklahoma Health Care Authority
April 2023

Market News and Updates[1,2,3,4,5]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **June 2022:** The FDA approved Pheburane® (sodium phenylbutyrate) oral pellets as adjunctive therapy to standard of care for adult and pediatric patients with urea cycle disorders (UCD). It is supplied as 483mg/g of sodium phenylbutyrate oral coated pellets. Pheburane® is a special formulation of "palatable pellets" which have a coating that masks the taste and a sugar core. The FDA approval was based on Buphenyl® (sodium phenylbutyrate) clinical data and a cohort study that surveyed patients' preferences of the products with a conclusion that the taste-masked pellets enhanced adherence and confirmed overall safety and effectiveness of Pheburane®.
- **December 2022:** The FDA approved Olpruva™ (sodium phenylbutyrate) pellets for oral suspension as adjunctive therapy to standard of care for the chronic management of UCDs. Olpruva™ pellets are covered by a sealed coating and an outer polymer coating that is packaged in a kit for reconstitution and is intended to mask the taste of sodium phenylbutyrate. The FDA approval was based on previous clinical study data and comparison data to Buphenyl® (sodium phenylbutyrate) powder for bioequivalence.

Cost Comparison: UCD Medications

Product	Cost Per Unit†	Cost Per Month*
Ravicti® (glycerol phenylbutyrate) 1.1g/mL solution	$219.13	$115,043.25
Pheburane® (sodium phenylbutyrate) 0.483g/g pellet	**$25.14**	**$31,229.81**
sodium phenylbutyrate 500mg tablet	$19.84	$23,808.00
sodium phenylbutyrate 0.94g/g powder	$16.91	$10,793.62

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Cost information for Olpruva™ is currently not available.
†Unit = each gram for Pheburane® pellets and sodium phenylbutyrate powder, each mL for Ravicti®, and each tablet for sodium phenylbutyrate tablets.
*Cost per month is based on a 30-day supply at maximum FDA approved dosing for each product.

Recommendations

The College of Pharmacy recommends the prior authorization of Olpruva™ (sodium phenylbutyrate) and Pheburane® (sodium phenylbutyrate) with the following criteria (shown in red):

Olpruva™ (Sodium Phenylbutyrate Pellets for Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
5. A maximum daily dose of 20g of sodium phenylbutyrate will apply.

Pheburane® (Sodium Phenylbutyrate Oral Pellets) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
4. A maximum daily dose of 20g of sodium phenylbutyrate will apply; and
5. A quantity limit of 1,218g of pellets (equivalent to 588g of sodium phenylbutyrate) per 29 days will apply.

Additionally, the College of Pharmacy recommends updating the Ravicti® (glycerol phenylbutyrate) approval criteria based on net costs (changes shown in red):

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and

4. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
5. A maximum daily dose of 17.5mL (19g) of glycerol phenylbutyrate will apply; and
6. A quantity limit of 525mL per 30 days will apply.

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[1] Pheburane® (Sodium Phenylbutyrate) – New Orphan Drug Approval. OptumRx®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_pheburane_2022-0628.pdf. Issued 06/17/2022. Last accessed 03/28/2023.
[2] Pheburane® (Sodium Phenylbutyrate) Prescribing Information. Medunik USA, Inc. Available online at: https://olpruva.com/wp-content/uploads/OLPRUVA-Prescribing-Information.pdf. Last revised 06/2022. Last accessed 03/28/2023.
[3] Kibleur Y, Guffon N. Long-Term Follow-Up on a Cohort Temporary Utilization Authorization (ATU) Survey of Patients Treated with Pheburane® (Sodium Phenylbutyrate) Taste-Masked Granules. *Paediatr Drugs* 2016; 18(2):139-44. doi: 10.1007/s40272-015-0159-8.
[4] Acer Therapeutics, Inc. Acer Therapeutics and Relief Therapeutics Announce U.S. FDA Approval of Olpruva™ for Patients with Urea Cycle Disorders. Available online at: https://www.acertx.com/2022/12/27/acer-therapeutics-and-relief-therapeutics-announce-u-s-fda-approval-of-olpruvafor-patients-with-urea-cycle-disorders/. Issued 12/27/2022. Last accessed 02/22/2023.
[5] Olpruva™ (Sodium Phenylbutyrate) Prescribing Information. Acer Therapeutics, Inc. Available online at: https://olpruva.com/wp-content/uploads/OLPRUVA-Prescribing-Information.pdf. Last revised 12/2022. Last accessed 03/28/2023.

Appendix H

Vote to Prior Authorize Jaypirca™ (Pirtobrutinib) and Lunsumio™ (Mosunetuzumab-axgb) and Update the Approval Criteria for the Lymphoma Medications

Oklahoma Health Care Authority
April 2023

Market News and Updates[1,2,3,4,5,6,7,8,9]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **June 2022:** The FDA approved a new indication for Breyanzi® (lisocabtagene maraleucel) for adults with large B-cell lymphoma (LBCL) who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age. Breyanzi® is not indicated for the treatment of patients with primary central nervous system lymphoma.
- **November 2022:** The FDA approved a new indication for Adcetris® (brentuximab vedotin) in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide for pediatric patients 2 years of age and older with previously untreated high risk classical Hodgkin lymphoma (cHL). This is the first pediatric approval for Adcetris®.
- **December 2022:** The FDA granted accelerated approval to Lunsumio™ (mosunetuzumab-axgb), a bispecific CD20-directed CD3 T-cell engager, for adults with relapsed or refractory follicular lymphoma (FL) after 2 or more lines of systemic therapy.
- **January 2023:** The FDA approved a new indication for Brukinsa® (zanubrutinib) for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- **January 2023:** The FDA granted accelerated approval to Jaypirca™ (pirtobrutinib) for relapsed or refractory mantle cell lymphoma (MCL) after at least 2 lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.

News:

- **December 2021:** Secura Bio, the manufacturer of Copiktra® (duvelisib), announced the voluntary withdrawal of the previous accelerated approval for relapsed or refractory FL, citing the current treatment landscape for FL and the logistics, cost, and timing of the post-marketing requirements for the FL indication. The withdrawal decision

was not based on any changes in the efficacy or safety of Copiktra®. Copiktra® remains FDA approved for the treatment of adults with relapsed or refractory CLL or SLL after at least 2 prior therapies.

- **June 2022:** The FDA announced its previous accelerated approvals for Ukoniq® (umbralisib) for FL and marginal zone lymphoma (MZL) have been withdrawn due to safety concerns. In February 2022, a Drug Safety Communication was issued stating the FDA was investigating a possible increased risk of death with Ukoniq®, and enrollment into the ongoing clinical trials with Ukoniq® had been suspended while the safety data was reviewed. Following this, additional findings from the Phase 3 UNITY-CLL clinical trial in patients with CLL continued to show a possible increased risk of death in patients receiving Ukoniq®, and the FDA determined the risk of treatment with Ukoniq® outweighed its benefits. As a result, TG Therapeutics, the manufacturer of Ukoniq®, has voluntarily withdrawn the medication from the market for its FL and MZL indications.

Guideline Update(s):

- **November 2022:** The National Comprehensive Cancer Network (NCCN) guidelines were updated to include brentuximab in combination with nivolumab as an option for second-line and subsequent therapy for patients with relapsed or refractory cHL. In a Phase 1/2 study of 91 patients with relapsed or refractory cHL, the combination of nivolumab with brentuximab resulted in an objective response rate (ORR) of 85% [with 67% achieving a complete response (CR)]. At a median follow-up of 34 months, the 3-year progression-free survival (PFS) and overall survival (OS) rates were 77% and 93%, respectively. The NCCN guidelines also recommend brentuximab in combination with bendamustine in this setting.

Jaypirca™ (Pirtobrutinib) Product Summary[10]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with relapsed or refractory MCL after at least 2 lines of systemic therapy, including a BTK inhibitor

How Supplied: 50mg and 100mg oral tablets

Dose:

- Recommended dose is 200mg [(2) 100mg tablets] once daily
- Dose reduction to 100mg or 50mg once daily is recommended for specific adverse reactions, severe renal impairment, or certain drug interactions

Cost: The Wholesale Acquisition Cost (WAC) is $350 per 100mg tablet, resulting in a monthly cost of $21,000 and a yearly cost of $252,000 based on the recommended dose of 200mg once daily.

Lunsumio™ (Mosunetuzumab-axgb) Product Summary[11]

Therapeutic Class: Bispecific CD20-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with relapsed or refractory FL after 2 or more lines of systemic therapy

How Supplied: 1mg/mL solution in 1mL and 30mL single-dose vials (SDVs)

Dosing and Administration:

- Administered in 21-day treatment cycles by intravenous (IV) infusion
- Cycle 1: 1mg on day 1, 2mg on day 8, and 60mg on day 15
- Cycle 2: 60mg on day 1
- Cycle 3 (and subsequent cycles): 30mg on day 1

Cost: The WAC is $594.06 per milliliter, resulting in a cost of $37,425.78 for the first cycle, $35,643.60 for the second cycle, and $17,821.80 for the third and subsequent cycles based on recommended dosing. This results in an estimated cost of $340,396.38 for the first year of treatment.

Recommendations

The College of Pharmacy recommends the prior authorization of Jaypirca™ (pirtobrutinib) and Lunsumio™ (mosunetuzumab-axgb) with the following criteria (shown in red):

Jaypirca™ (Pirtobrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy; and
3. Previous treatment must have included a Bruton's tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, zanubrutinib).

Lunsumio™ (Mosunetuzumab-axgb) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy.

Additionally, the College of Pharmacy recommends updating the Adcetris® (brentuximab vedotin), Breyanzi® (lisocabtagene maraleucel), Brukinsa® (zanubrutinib), Tecartus® (brexucabtagene autoleucel), and Yescarta® (axicabtagene ciloleucel) criteria based on the recent FDA approvals, NCCN guideline recommendations, and to be consistent with the other chimeric

antigen receptor (CAR) T-cell therapies (new criteria and changes shown in red):

Adcetris® (Brentuximab Vedotin) Approval Criteria [Classical Hodgkin Lymphoma (cHL) Diagnosis]:

1. For members 18 years of age or older:
    a. In previously untreated Stage III or IV disease in combination with doxorubicin, vinblastine, and dacarbazine; or
    b. In relapsed/refractory disease after failure of ≥2 multi-agent chemotherapy regimens in non-autologous stem cell transplant (SCT) candidates or after failure of autologous SCT as a single-agent; or
    c. In relapsed/refractory disease if not previously used in combination with nivolumab, bendamustine, or multi-agent chemotherapy; or
    d. Consolidation following autologous SCT in members at high risk of relapse or progression; or
2. For members 2 to 21 years of age:
    a. Diagnosis of previously untreated cHL; and
    b. Stage IIB with bulky disease, Stage IIIB, or Stage IV per Ann Arbor staging system; and
    c. Used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide (AVE-PC); and
    d. Maximum of (5) 21-day cycles will be approved.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma; and
    a. One of the following:
        i. Refractory disease to frontline chemoimmunotherapy; or
        ii. Relapse within 12 months of frontline chemoimmunotherapy; or
        iii. Relapse after frontline chemoimmunotherapy and member is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidity or age; or
        iv. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
~~2. Relapsed or refractory disease; and~~
~~3. Member must have received at least 2 lines of systemic therapy; and~~
4. Member does not have primary central nervous system (CNS) lymphoma; and
5. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply

with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
6. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene ciloleucel) is not appropriate for the member must be provided; and
7. Approvals will be for 1 dose per member per lifetime.

Brukinsa® (Zanubrutinib) Approval Criteria [Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Diagnosis]:
1. Diagnosis of CLL/SLL.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:
1. Diagnosis of acute lymphoblastic leukemia (ALL); and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
4. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Lymphoma Diagnosis]:
1. Diagnosis of mantle cell lymphoma; and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
4. Approvals will be for 1 dose per member per lifetime.

Yescarta® (Axicabtagene Ciloleucel) Approval Criteria [Lymphoma Diagnosis]:
1. Diagnosis of large B-cell lymphoma [including diffuse large B cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Member must be 18 years of age or older; and
3. Relapsed or refractory disease used in 1 of the following settings:
    a. After 2 or more lines of therapy; or
    b. After 1 line of therapy, if member is refractory to first-line chemotherapy or relapses within 12 months of first-line chemotherapy; and

4. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
5. For large B-cell lymphoma (including DLBCL, high grade B-cell lymphoma, and DLBCL arising from FL), member must not have primary central nervous system lymphoma; and
6. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends the removal of criteria for Copiktra® (duvelisib) for FL and the removal of criteria for Ukoniq® (umbralisib) for FL and MZL based on the FDA withdrawal of the accelerated approvals for these indications (changes shown in red):

~~**Copiktra® (Duvelisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

~~1. Relapsed/refractory FL; and~~
~~2. Progression of disease following 2 or more lines of systemic therapy; and~~
~~3. As a single agent.~~

~~**Ukoniq® (Umbralisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

~~1. Diagnosis of FL; and~~
~~2. Relapsed or refractory disease; and~~
~~3. Member must have received at least 3 prior lines of systemic therapy.~~

~~**Ukoniq® (Umbralisib) Approval Criteria [Marginal Zone Lymphoma (MZL) Diagnosis]:**~~

~~1. Diagnosis of MZL; and~~
~~2. Relapsed or refractory disease; and~~
~~3. Member must have received at least 1 prior anti-CD20-based regimen.~~

[1] U.S. Food and Drug Administration (FDA). FDA Approves Lisocabtagene Maraleucel for Second-Line Treatment of Large B-Cell Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-lisocabtagene-maraleucel-second-line-treatment-large-b-cell-lymphoma. Issued 06/24/2022. Last accessed 03/21/2023.
[2] U.S. FDA. FDA Approves Brentuximab Vedotin in Combination with Chemotherapy for Pediatric Patients with Classical Hodgkin Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-brentuximab-vedotin-combination-chemotherapy-pediatric-patients-classical-hodgkin. Issued 11/10/2022. Last accessed 03/21/2023.
[3] U.S. FDA. FDA Grants Accelerated Approval to Mosunetuzumab-axgb for Relapsed or Refractory Follicular Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mosunetuzumab-axgb-relapsed-or-refractory-follicular-lymphoma. Issued 12/22/2022. Last accessed 03/21/2023.
[4] U.S. FDA. FDA Approves Zanubrutinib for Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-zanubrutinib-chronic-lymphocytic-leukemia-or-small-lymphocytic-lymphoma. Issued 01/19/2023. Last accessed 03/21/2023.
[5] U.S. FDA. FDA Grants Accelerated Approval to Pirtobrutinib for Relapsed or Refractory Mantle Cell Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-pirtobrutinib-relapsed-or-refractory-mantle-cell-lymphoma. Issued 01/27/2023. Last accessed 03/21/2023.
[6] Secura Bio, Inc. Secura Bio Announces Copiktra® (Duvelisib) Strategic Focus on T-cell Lymphoma and Voluntary U.S. Withdrawal of the Relapsed or Refractory Follicular Lymphoma Indication. Available online at: https://www.prnewswire.com/news-releases/secura-bio-announces-copiktra-duvelisib-strategic-focus-on-t-cell-lymphoma-and-voluntary-us-withdrawal-of-the-relapsed-or-refractory-follicular-lymphoma-indication-301436834.html. Issued 12/03/2021. Last accessed 03/21/2023.
[7] U.S. FDA. FDA Approval of Lymphoma Medicine Ukoniq® (Umbralisib) is Withdrawn due to Safety Concerns. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-approval-lymphoma-medicine-ukoniq-umbralisib-withdrawn-due-safety-concerns. Issued 06/01/2022. Last accessed 03/21/2023.
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[9] Advani RH, Moskowitz AJ, Bartlett NL, et al. Brentuximab Vedotin in Combination with Nivolumab in Relapsed or Refractory Hodgkin Lymphoma: 3-Year Study Results. *Blood* 2021; 138(6):427-438.
[10] Jaypirca™ (Pirtobrutinib) Prescribing Information. Eli Lilly and Company. Available online at: https://pi.lilly.com/us/jaypirca-uspi.pdf?s=pi. Last revised 01/2023. Last accessed 03/21/2023.
[11] Lunsumio™ (Mosunetuzumab-axgb) Prescribing Information. Genentech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761263s000lbl.pdf. Last revised 12/2022. Last accessed 03/21/2023.

Appendix I

Calendar Year 2022 Annual Review of Hereditary Angioedema (HAE) Medications

Oklahoma Health Care Authority
April 2023

Current Prior Authorization Criteria

Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), Orladeyo® (Berotralstat), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Authorization of Cinryze® or Haegarda® will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo®; and
7. Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, or Orladeyo®; and
8. Cinryze® Dosing:
    a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
    b. Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and
    c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); or
9. Haegarda® Dosing:
    a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
    b. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
    c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or

10. Orladeyo® Dosing:
    a. The recommended dose of Orladeyo® is 150mg by mouth once daily; and
    b. A quantity limit of 28 capsules per 28 days will apply; or
11. Takhzyro® Dosing:
    a. The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    b. Prescriber must verify member or caregiver has been trained by a health care professional on proper storage and sub-Q administration of Takhzyro®; and
    a. A quantity limit of (2) 300mg/2mL vials per 28 days will apply.

Berinert® (C1 Esterase Inhibitor), Firazyr® (Icatibant), Kalbitor® (Ecallantide), and Ruconest® (C1 Esterase Inhibitor) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for the treatment of acute attacks of HAE; and
3. For authorization consideration of Firazyr® (icatibant) or Kalbitor® (ecallantide), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor) must be provided; or
4. For authorization consideration of Ruconest® (C1 esterase inhibitor), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor), Firazyr® (icatibant), or Kalbitor® (ecallantide) must be provided.

Utilization of HAE Medications: Calendar Year 2022

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	4	18	$596,994.70	$33,166.37	$1,854.02	114	322
2022	2	6	$2,973.83	$495.64	$17.70	26	168
% Change	**-50.00%**	**-66.7%**	**-99.5%**	**-98.5%**	**-99.0%**	**-77.2%**	**-47.8%**
Change	**-2**	**-12**	**-$594,020.87**	**-$32,670.73**	**-$1,836.32**	**-88**	**-154**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: Most paid pharmacy claims during calendar year 2022 were claims for which SoonerCare was not the primary payer; therefore, the reimbursed amount included in the above data is not a true reflection of the medication cost.

Calendar Year 2022 Utilization: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2022	1	1	$5,733.00	$5,733.00	100

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
There was no SoonerCare medical claims of HAE medications in calendar year 2021 to allow for a calendar year comparison.

Demographics of Members Utilizing HAE Medications

- Due to the limited number of members utilizing HAE medications during calendar year 2022, detailed demographic information could not be provided.

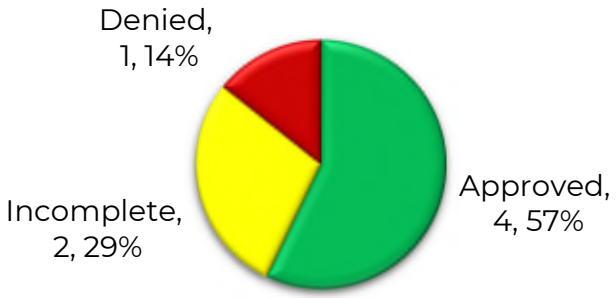
Top Prescriber Specialties of HAE Medications by Number of Claims

- There were 6 pharmacy claims for HAE medications during calendar year 2022, all of which were prescribed by allergists.

Prior Authorization of HAE Medications

There were 7 prior authorization requests submitted for HAE medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Orladeyo® (berotralstat): November 2039

New U.S. Food and Drug Administration (FDA) Approval(s):

- **February 2023:** The FDA approved Takhzyro® (lanadelumab-flyo) for an age expansion for prophylaxis to prevent HAE attacks in children 2 to 12 years of age. Takhzyro® was previously FDA approved for this indication in August 2018 in patients 12 years of age and older.

Recommendations

The College of Pharmacy recommends the following changes to the current HAE prophylactic medications prior authorization criteria based on the FDA approved age expansion for Takhzyro® (lanadelumab-flyo) (changes shown in red):

Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), Orladeyo® (Berotralstat), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Authorization of Cinryze® or Haegarda® will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo®; and
7. Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, or Orladeyo®; and
8. Cinryze® Dosing:
    a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
    b. Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and
    c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); or
9. Haegarda® Dosing:
    a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
    b. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
    c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or
10. Orladeyo® Dosing:
    a. The recommended dose of Orladeyo® is 150mg by mouth once daily; and

b. A quantity limit of 28 capsules per 28 days will apply; or

11. Takhzyro® Dosing:
    a. For members 12 years of age and older: The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    b. For members 6 to 11 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    c. For members 2 to 5 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 4 weeks; and
    d. Prescriber must verify member or caregiver has been trained by a health care professional on proper storage and sub-Q administration of Takhzyro®; and
    e. A quantity limit of (2) ~~300mg/2mL~~ vials per 28 days will apply.

Utilization Details of HAE Medications: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TAKHZYRO INJ 300MG/2ML⁺	5	1	$166.42	$33.28	5	5.60%
ICATIBANT INJ 30MG/3ML	1	1	$2,807.41	$2,807.41	1	94.40%
TOTAL	**6**	**2***	**$2,973.83**	**$495.64**	**3**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Claims for Takhzyro® during calendar year 2022 consist of claims for 1 member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.
INJ = injection

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BERINERT INJ 500 UNIT J0597	1	1	$5,733.00	$5,733.00	1	100%
TOTAL	**1**	**1**	**$5,733.00**	**$5,733.00**	**1**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 03/2023. Last accessed 03/28/2023.
[2] Longhurst H. FDA Approves Expanded Use of Takhzyro® for Children with Hereditary Angioedema. Available online at: https://www.healio.com/news/allergy-asthma/20230207/fda-approves-expanded-use-of-takhzyro-for-children-with-hereditary-angioedema. Issued 02/07/2023. Last accessed 03/22/2023.

Appendix J

Calendar Year 2022 Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Imjudo® (Tremelimumab-actl) and Krazati® (Adagrasib)

Oklahoma Health Care Authority
April 2023

Current Prior Authorization Criteria

Utilization data for Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), Opdivo® (nivolumab), Tafinlar® (dabrafenib), Yervoy® (ipilimumab), and Zelboraf® (vemurafenib) and approval criteria for indications other than lung cancer can be found in the December 2022 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki) and approval criteria for indications other than lung cancer can be found in the September 2022 DUR Board packet. Enhertu® (fam-trastuzumab deruxtecan-nxki) is reviewed annually with the breast cancer medications.

Alecensa® (Alectinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of recurrent or metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity; and
3. First-line or recurrent setting; and
4. As a single agent only.

Alunbrig® (Brigatinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity.

Cosela™ (Trilaciclib) Approval Criteria [Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. Member is undergoing myelosuppressive chemotherapy with 1 of the following:
    a. Platinum (carboplatin or cisplatin) and etoposide-containing regimen; or
    b. Topotecan-containing regimen.

Cyramza® (Ramucirumab) Approval Criteria [Colorectal Cancer Diagnosis]:

1. Diagnosis of colorectal cancer; and

2. Subsequent therapy for metastatic disease after progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine; and
3. In combination with an irinotecan-based regimen.

Cyramza® (Ramucirumab) Approval Criteria [Esophageal Cancer Diagnosis]:

1. Diagnosis of unresectable, locally advanced, recurrent, or metastatic esophageal or esophagogastric junction adenocarcinoma; and
2. Karnofsky performance score ≥60%; and
3. As a single agent or in combination with paclitaxel.

Cyramza® (Ramucirumab) Approval Criteria [Gastric Cancer Diagnosis]:

1. Diagnosis of gastric cancer; and
2. Member is not a surgical candidate or has unresectable, locally advanced, recurrent, or metastatic disease; and
3. Karnofsky performance score ≥60%; and
4. As a single agent or in combination with paclitaxel.

Cyramza® (Ramucirumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Second-line or greater therapy; and
3. Previously failed sorafenib; and
4. Alpha-fetoprotein concentration ≥400ng/mL; and
5. As a single agent.

Cyramza® (Ramucirumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. First-line in combination with erlotinib; and
    a. Epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation; or
3. Subsequent therapy for metastatic disease; and
    a. In combination with docetaxel.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Unresectable or metastatic NSCLC; and
2. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member must have received a prior systemic therapy.

Exkivity® (Mobocertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced or metastatic NSCLC; and

2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
3. Disease has progressed on or after platinum-based chemotherapy; and
4. As a single agent.

Gavreto® (Pralsetinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC in adults; and
2. Recurrent, advanced, or metastatic disease; and
3. Rearranged during transfection (RET) fusion-positive tumor.

Gavreto® (Pralsetinib) Approval Criteria [Thyroid Cancer Diagnosis]:

1. Adult and pediatric members 12 years of age and older; and
2. Diagnosis of advanced or metastatic disease with either:
    a. Rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC) requiring systemic therapy; or
    b. RET fusion-positive thyroid cancer requiring systemic therapy and member is radioactive iodine-refractory (if radioactive iodine is appropriate).

Gilotrif® (Afatinib) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of head and neck cancer; and
2. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
3. Non-nasopharyngeal cancer must be 1 of the following:
    a. Newly diagnosed T4b, any N, M0 disease, unresectable nodal disease with no metastases, or for members who are unfit for surgery and have a performance status (PS) of 3; or
    b. Metastatic (M1) disease at initial presentation, recurrent/persistent disease with distant metastases, or unresectable locoregional recurrence or second primary with prior radiation therapy (RT) and PS of 0 to 2; or
    c. Unresectable locoregional recurrence without prior RT and PS of 3; and
4. As a single agent only.

Gilotrif® (Afatinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. For first-line therapy, meeting the following:
    a. Epidermal growth factor receptor (EGFR) mutation detected; and
    b. As a single agent only; or
3. For second-line therapy, meeting the following:
    a. Progressed following platinum-based chemotherapy; and

b. As a single agent or in combination with cetuximab in members with a known sensitizing EGFR mutation who are T790M negative.

Imfinzi® (Durvalumab) Approval Criteria [Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. In combination with etoposide and either cisplatin or carboplatin followed by single agent maintenance.

Imfinzi® (Durvalumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of unresectable stage II or III NSCLC; and
2. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Keytruda® (Pembrolizumab) Approval Criteria [Metastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression as follows:
    a. As a single agent, first-line: ≥1%; or
    b. First-line in combination: no expression required; or
    c. As a single agent, second-line: ≥1%; and
4. Member meets 1 of the following:
    a. Previously untreated, metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel; or
    b. Previously untreated, metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin; or
    c. New diagnosis as first-line therapy (member has not received chemotherapy to treat disease) if:
        i. Tumor does not express sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations; or
    d. As a single agent for disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin):
        i. Members with EGFR-mutation-positive tumors should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations*; and
            1. *Examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib; or*
        ii. Members with ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these

aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations*; and
    1. *Examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib*.

Keytruda® (Pembrolizumab) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of stage III nonmetastatic NSCLC; and
2. Ineligible for surgery or definitive chemoradiation; and
3. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression ≥1%; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:
1. Diagnosis of metastatic SCLC; and
2. Progressed on or following a platinum-based regimen and at least 1 other regimen; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of advanced, unresectable, or metastatic NSCLC; and
2. Used in the first-line setting; and
3. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 mutations; and
4. Used in 1 of the following settings:
    a. Used as a single agent; and
        i. High programmed death ligand 1 (PD-L1) expression [tumor proportion score (TPS) ≥50%]; or
    b. Used in combination with platinum-based chemotherapy; and
        i. No requirement for PD-L1 expression.

Lorbrena® (Lorlatinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of metastatic NSCLC; and
2. Tumor expresses anaplastic lymphoma kinase (ALK) translocation; and
3. As a single agent as first-line therapy; or
4. As a single agent as second-line therapy following disease progression on either alectinib or ceritinib; or
5. As a single agent as third-line or greater therapy following disease progression on crizotinib and 1 other ALK inhibitor (i.e., ceritinib, alectinib).

Lumakras® (Sotorasib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Presence of *KRAS G12C* mutation; and
3. Disease has progressed on at least 1 prior systemic therapy; and
4. As a single agent.

Mekinist® (Trametinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type BRAF NSCLC; and
3. In combination with dabrafenib.

Opdivo® (Nivolumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with ipilimumab.

Opdivo® (Nivolumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
2. For first-line therapy for recurrent, advanced, or metastatic disease, meeting the following:
    a. Used in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. Expresses programmed death ligand 1 (PD-L1) ≥1%; or
3. For first-line therapy for resectable disease (>4cm or node positive), meeting the following:
    a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles; or
4. For second-line therapy for metastatic disease, meeting the following:
    a. Tumor histology is 1 of the following:
        i. Adenocarcinoma; or
        ii. Squamous cell; or
        iii. Large cell; and
    b. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
    d. Used as a single agent; and
    e. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. Member meets 1 of the following:
    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease progression on initial chemotherapy; and
3. As a single agent or in combination with ipilimumab; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Pemfexy® (Pemetrexed) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed) must be provided.

Retevmo® (Selpercatinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Rearranged during transfection (RET) fusion-positive tumor; and
3. As a single agent.

Retevmo® (Selpercatinib) Approval Criteria [Thyroid Cancer Diagnosis]:

1. Adult and pediatric members 12 years of age and older; and
2. As a single agent; and
3. Diagnosis of advanced or metastatic disease with either:
    a. Rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC) requiring systemic therapy; or
    b. RET fusion-positive thyroid cancer requiring systemic therapy and member is radioactive iodine-refractory (if radioactive iodine is appropriate).

Rozlytrek® (Entrectinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. *ROS1*-positive.

Rozlytrek® (Entrectinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of solid tumors; and
2. Member must be 12 years of age or older; and
3. Neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation; and
4. Metastatic or not a surgical candidate; and
5. Progressed following treatment or have no satisfactory alternative therapy.

Rybrevant® (Amivantamab-vmjw) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
3. Disease has progressed on or after platinum-based chemotherapy; and
4. As a single agent.

Tabrecta® (Capmatinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Mesenchymal-epithelial transition (MET) exon 14 skipping positive tumor; and
3. As a single agent.

Tafinlar® (Dabrafenib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
    a. Not indicated for wild-type BRAF NSCLC; and
3. As a single agent or in combination with trametinib.

Tagrisso® (Osimertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
    a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; or
2. Diagnosis of metastatic NSCLC; and
    a. EGFR T790M mutation-positive disease; or
    b. EGFR exon 19 deletions or exon 21 L858R mutations.

Tarceva® (Erlotinib) Approval Criteria [Bone Cancer – Chordoma Diagnosis]:

1. Diagnosis of bone cancer – chordoma; and
2. Recurrent disease; and
3. As a single agent only.

Tarceva® (Erlotinib) Approval Criteria [Kidney Cancer Diagnosis]:

1. Diagnosis of kidney cancer; and
2. Non-clear cell type; and
3. Relapsed disease or surgically unresectable stage IV disease; and
4. As a single agent only.

Tarceva® (Erlotinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
2. Recurrent or metastatic disease; and
3. Epidermal growth factor receptor (EGFR) mutation detected; and
4. As a single agent only.

Tarceva® (Erlotinib) Approval Criteria [Pancreatic Adenocarcinoma Diagnosis]:

1. Diagnosis of pancreatic adenocarcinoma; and
2. Locally advanced, unresectable disease or metastatic disease; and
3. In combination with gemcitabine.

Tarceva® (Erlotinib) Approval Criteria [Pancreatic Cancer Diagnosis]:

1. Diagnosis of pancreatic cancer; and
2. Locally advanced unresectable or metastatic disease; and
3. First-line agent only; and
4. In combination with gemcitabine.

Tecentriq® (Atezolizumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of advanced unresectable or metastatic disease; and
2. Used in combination with bevacizumab; and
3. Member has not received prior systemic therapy.

Tecentriq® (Atezolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Unresectable or metastatic disease; and
2. BRAF V600 mutation-positive; and
3. In combination with cobimetinib and vemurafenib.

Tecentriq® (Atezolizumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of Non-Squamous NSCLC:
    a. First-line therapy for metastatic disease; and
    b. Member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), *ROS1*, *BRAF*, MET exon 14 skipping, or rearranged during transfection (RET) mutations; and
    c. Used in combination with bevacizumab, paclitaxel, and carboplatin (maximum of 6 cycles) or in combination with paclitaxel (protein bound) and carboplatin; and
    d. Atezolizumab and bevacizumab may be continued after the above combination in members without disease progression (applies to the bevacizumab/paclitaxel/carboplatin regimen); or
2. Diagnosis of NSCLC:
    a. For first-line therapy for metastatic disease:

i. As a single agent; and
ii. Member does not have EGFR, ALK, *ROS1*, *BRAF*, MET exon 14 skipping, or RET mutations; and
iii. High programmed death ligand-1 (PD-L1) expression determined by 1 of the following:
1. PD-L1 stained ≥50% of tumor cells (TC≥50%); or
2. PD-L1 stained tumor-infiltrating immune cells (IC) covering ≥10% of the tumor area (IC≥10%); or

b. For subsequent therapy for metastatic disease:
i. As a single agent only; or

3. Diagnosis of stage II or IIIl3A NSCLC; and
a. Member has undergone resection and completed platinum-based chemotherapy; and
b. PD-L1 expression of ≥1% of TC.

Tecentriq® (Atezolizumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. First-line therapy; and
3. Extensive-stage disease; and
4. In combination with carboplatin and etoposide.

Tecentriq® (Atezolizumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Progressed on or following platinum-containing chemotherapy or cisplatin ineligible members.

Tepmetko® (Tepotinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced, metastatic, or unresectable NSCLC; and
2. Mesenchymal-epithelial transition (MET) exon 14 skipping positive tumor; and
3. As a single agent.

Vizimpro® (Dacomitinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Member has not received prior epidermal growth factor receptor (EGFR) therapy for metastatic disease; and
3. Members must meet 1 of the following:
a. EGFR exon 19 deletion; or
b. Exon 21 L858R substitution mutation.

Xalkori® (Crizotinib) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL) Diagnosis]:

1. Members 1 to 21 years of age:
    a. Diagnosis of systemic ALCL that is anaplastic lymphoma kinase (ALK)-positive; and
    b. Relapsed or refractory disease; or
2. Members older than 21 years of age:
    a. Diagnosis of systemic ALCL that is ALK-positive; and
    b. Second-line or initial palliative intent therapy and subsequent therapy.

Xalkori® (Crizotinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. First-line or subsequent therapy; and
3. Anaplastic lymphoma kinase (ALK) or *ROS1*-positive; or
4. MET amplification; and
5. As a single agent only.

Xalkori® (Crizotinib) Approval Criteria [Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) Diagnosis]:

1. Diagnosis of soft tissue sarcoma – IMT; and
2. Anaplastic lymphoma kinase (ALK) positive; and
3. Used as a single agent only.

Yervoy® (Ipilimumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
    a. Used for first-line therapy and must meet the following:
        i. Used in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy; and
        ii. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
        iii. Expresses programmed death ligand 1 (PD-L1) ≥1%.

Yervoy® (Ipilimumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. Member meets 1 of the following:

a. Disease relapsed within 6 months of initial chemotherapy; or
b. Disease is progressive on initial chemotherapy; and

3. In combination with nivolumab.

Zelboraf® (Vemurafenib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
   a. Not indicated for wild-type BRAF NSCLC; and
3. As a single agent.

Zepzelca® (Lurbinectedin) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of metastatic SCLC; and
2. Used following disease progression on or after platinum-based chemotherapy.

Zykadia® (Ceritinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity; and
3. As a single agent only.

Zykadia® (Ceritinib) Approval Criteria [Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) with Anaplastic Lymphoma Kinase (ALK) Translocation Diagnosis]:

1. Diagnosis of soft tissue sarcoma – IMT; and
2. ALK positivity; and
3. As a single agent only.

Utilization of Lung Cancer Medications: Calendar Year 2022

The following utilization data includes medications indicated for lung cancer; however, the data does not differentiate between lung cancer and other diagnoses, for which use may be appropriate.

Calendar Year Comparison: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	9	37	$564,513.52	$15,257.12	$508.57	5,310	1,110
2022	23	122	$2,031,155.02	$16,648.81	$550.45	15,510	3,690
% Change	**155.60%**	**229.70%**	**259.80%**	**9.10%**	**8.20%**	**192.10%**	**232.40%**
Change	**14**	**85**	**$1,466,641.50**	**$1,391.69**	**$41.88**	**10,200**	**2,580**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

Calendar Year Comparison: Medical Claims

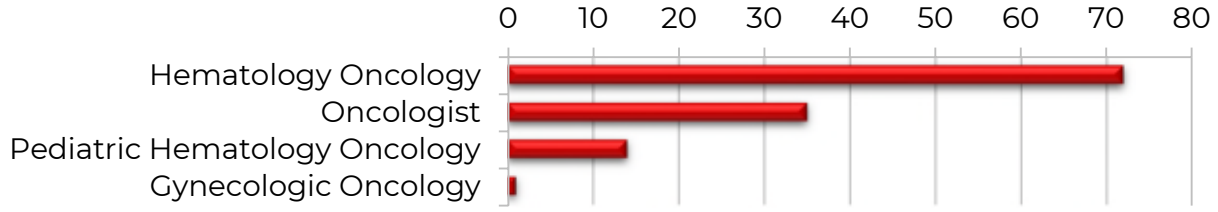
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	120	658	$4,027,672.99	$6,121.08	5.48
2022	175	1,069	$7,518,195.20	$7,032.92	6.11
% Change	**45.83%**	**62.46%**	**86.66%**	**14.90%**	**11.50%**
Change	**55**	**411**	**$3,490,522.21**	**$911.84**	**0.63**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

Demographics of Members Utilizing Lung Cancer Medications: Pharmacy Claims

- Due to the limited number of members utilizing lung cancer medications during calendar year 2022, detailed demographic information could not be provided.

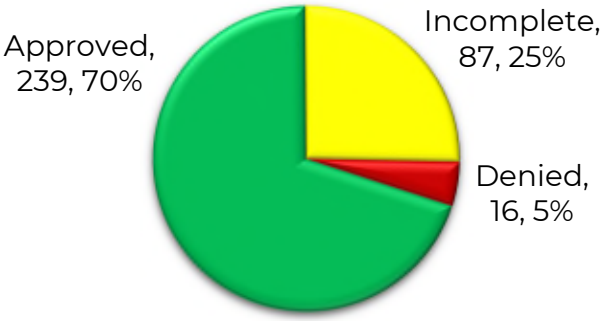
Top Prescriber Specialties of Lung Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Lung Cancer Medications

There were 342 prior authorization requests submitted for lung cancer medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2,3,4,5,6,7,8,9,10]

Anticipated Patent Expiration(s):

- Zepzelca® (lurbinectedin): December 2024
- Vizimpro® (dacomitinib): August 2028
- Xalkori® (crizotinib): November 2029
- Tepmetko® (tepotinib): March 2030
- Gilotrif® (afatinib): January 2031
- Zykadia® (ceritinib): February 2032
- Tagrisso® (osimertinib): January 2035
- Alecensa® (alectinib): April 2035
- Exkivity® (mobocertinib): May 2035
- Tabrecta® (capmatinib): July 2035
- Pemfexy® (pemetrexed): October 2035
- Alunbrig® (brigatinib): November 2035
- Krazati® (adagrasib): May 2037
- Rozlytrek® (entrectinib): July 2038
- Lorbrena® (lorlatinib): October 2038
- Retevmo® (selpercatinib): October 2038
- Gavreto® (pralsetinib): April 2039
- Cosela™ (trilaciclib): July 2039
- Lumakras® (sotorasib): August 2040

New U.S. Food and Drug Administration (FDA) Approval(s):

- **July 2022:** The FDA approved a new indication for Xalkori® (crizotinib) for adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory anaplastic lymphoma kinase (ALK)-positive myofibroblastic tumors (IMT).
- **September 2022:** The FDA approved a new indication for Imfinzi® (durvalumab) in combination with gemcitabine and cisplatin for adult patients with locally advanced or metastatic biliary tract cancer (BTC).
- **September 2022:** The FDA granted accelerated approval for a new indication for Retevmo® (selpercatinib) for adult patients with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.
- **October 2022:** The FDA approved Imjudo® (tremelimumab-actl) in combination with Imfinzi® (durvalumab) for adult patients with unresectable hepatocellular carcinoma (HCC).
- **November 2022:** The FDA approved a new indication for Imjudo® (tremelimumab-actl) in combination with Imfinzi® (durvalumab) and platinum-based chemotherapy for adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or ALK genomic tumor aberrations.

- **December 2022:** The FDA approved a new indication for Tecentriq® (atezolizumab) for adult and pediatric patients 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma (ASPS).
- **December 2022:** The FDA granted accelerated approval for Krazati® (adagrasib) for adult patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least 1 prior systemic therapy.
- **December 2022:** The FDA approved a new indication for Pemfexy® (pemetrexed) in combination with pembrolizumab and platinum-based chemotherapy for the initial treatment of patients with metastatic NSCLC with no EGFR or ALK genomic tumor aberrations.

News:

- **December 2022:** Genentech, the manufacturer of Tecentriq® (atezolizumab), announced the voluntary withdrawal of the previous accelerated approval for the treatment of adults with locally advanced or metastatic urothelial carcinoma. The withdrawal is based on the results of the required post-marketing study (IMvigor130), which did not meet the co-primary endpoint of overall survival (OS) for Tecentriq® plus chemotherapy compared with chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial carcinoma.

Imjudo® (Tremelimumab-actl) Product Summary[11]

Therapeutic Class: Cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody

Indication(s):

- Treatment of adult patients with unresectable HCC, in combination with durvalumab
- Treatment of adult patients with metastatic NSCLC with no sensitizing EGFR mutation or ALK genomic tumor aberrations, in combination with durvalumab and platinum-based chemotherapy

How Supplied:

- 25mg/1.25mL (20mg/mL) solution in a single-dose vial (SDV)
- 300mg/15mL (20mg/mL) solution in a SDV

Dose:

- HCC:
  - Weight ≥30kg: 300mg as a single dose in combination with durvalumab 1,500mg at cycle 1/day 1, followed by durvalumab as a single agent every 4 weeks

    - Weight <30kg: 4mg/kg as a single dose in combination with durvalumab 20mg/kg at cycle 1/day 1, followed by durvalumab as a single agent every 4 weeks
- NSCLC:
    - Weight ≥30kg: 75mg every 3 weeks in combination with durvalumab 1,500mg and platinum-based chemotherapy for 4 cycles, then administer durvalumab 1,500mg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo® 75mg in combination with durvalumab dose 6 at week 16
    - Weight <30kg: 1mg/kg every 3 weeks in combination with durvalumab 20mg/kg and platinum-based chemotherapy for 4 cycles, and then administer durvalumab 20mg/kg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo® 1mg/kg in combination with durvalumab dose 6 at week 16

Cost: The Wholesale Acquisition Cost (WAC) is $2,600 per milliliter. For the treatment of HCC, this results in a cost of $39,000 for the single treatment dose of 300mg for a member weighing ≥30kg. For the treatment of NSCLC, this results in a cost of $9,750 per dose or $48,750 for the recommended 5 doses for a member weighing ≥30kg.

Krazati® (Adagrasib) Product Summary[12]

Therapeutic Class: Inhibitor of RAS GTPase

Indication(s): Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA approved test, who have received at least 1 prior systemic therapy

How Supplied: 200mg oral tablets

Dose: 600mg [(3) 200mg tablets] twice daily

Cost: The WAC is $109.72 per tablet, resulting in a cost of $19,749.60 per 30 days and $236,995.20 per year based on the recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Imjudo® (tremelimumab-actl) and Krazati® (adagrasib) based on recent FDA approvals with the following criteria (shown in red):

Imjudo® (Tremelimumab-actl) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of unresectable HCC; and

2. Used in combination with durvalumab; and
3. Will be approved for a maximum of 1 dose per treatment plan per member.

Imjudo® (Tremelimumab-actl) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 mutations; and
3. Used in combination with durvalumab and platinum-based chemotherapy; and
4. Will be approved for a maximum of 5 doses per treatment plan per member.

Krazati® (Adagrasib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Presence of KRAS G12C mutation in tumor or plasma specimen as determined by an FDA approved test; and
3. Member has received at least 1 prior systemic therapy; and
4. As a single agent.

The College of Pharmacy also recommends updating the Imfinzi® (durvalumab), Retevmo® (selpercatinib), Tecentriq® (atezolizumab), and Xalkori® (crizotinib) approval criteria based on new FDA approvals (changes shown in red):

Imfinzi® (Durvalumab) Approval Criteria [Biliary Tract Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic biliary tract cancer; and
2. Used in combination with gemcitabine and cisplatin.

Imfinzi® (Durvalumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of unresectable HCC; and
2. Used in combination with tremelimumab-actl.

Imfinzi® (Durvalumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of unresectable stage II or III NSCLC; and
    a. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; or
2. Diagnosis of metastatic NSCLC; and
    a. No epidermal growth factor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    b. Used in combination with tremelimumab-actl and platinum-based chemotherapy.

Retevmo® (Selpercatinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of locally advanced or metastatic solid tumor; and
2. Rearranged during transfection (RET) gene fusion; and
    a. Disease has progressed on or following prior systemic treatment; or
    b. There are no satisfactory alternative treatment options; and
3. As a single agent.

Tecentriq® (Atezolizumab) Approval Criteria [Alveolar Soft Part Sarcoma (ASPS) Diagnosis]:

1. Diagnosis of unresectable or metastatic ASPS; and
2. Member must be 2 years of age or older.

Xalkori® (Crizotinib) Approval Criteria [Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) Diagnosis]:

1. Diagnosis of soft tissue sarcoma – IMT; and
2. Member must be 1 year of age or older; and
3. Anaplastic lymphoma kinase (ALK) positive; and
4. Used as a single agent only.

Next, the College of Pharmacy recommends updating the Alunbrig® (brigatinib), Gavreto® (pralsetinib), Rozlytrek® (entrectinib), Tagrisso® (osimertinib), Vizimpro® (dacomitinib), and Xalkori® (crizotinib) approval criteria to be more consistent with clinical practice and to clarify appropriate use as a single agent (changes shown in red):

Alunbrig® (Brigatinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity; and
3. As a single agent.

Gavreto® (Pralsetinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC in adults; and
2. Recurrent, advanced, or metastatic disease; and
3. Rearranged during transfection (RET) fusion-positive tumor; and
4. As a single agent.

Gavreto® (Pralsetinib) Approval Criteria [Thyroid Cancer Diagnosis]:

1. Adult and pediatric members 12 years of age and older; and
2. Diagnosis of advanced or metastatic disease with either:
    a. Rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC) requiring systemic therapy; or
    b. RET fusion-positive thyroid cancer requiring systemic therapy and member is radioactive iodine-refractory (if radioactive iodine is appropriate); and

3. As a single agent.

Rozlytrek® (Entrectinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. *ROS1*-positive; and
3. As a single agent.

Rozlytrek® (Entrectinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of solid tumors; and
2. Member must be 12 years of age or older; and
3. Neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation; and
4. Metastatic or not a surgical candidate; and
5. Progressed following treatment or have no satisfactory alternative therapy; and
6. As a single agent.

Tagrisso® (Osimertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
    a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; or
2. Diagnosis of metastatic NSCLC; and
    a. EGFR T790M mutation-positive disease; or
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and
3. As a single agent.

Vizimpro® (Dacomitinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Member has not received prior epidermal growth factor receptor (EGFR) therapy for metastatic disease; and
3. Members must meet 1 of the following:
    a. EGFR exon 19 deletion; or
    b. Exon 21 L858R substitution mutation; and
4. As a single agent.

Xalkori® (Crizotinib) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL) Diagnosis]:

1. Members ~~1 to 21 years of age~~ 1 year of age or older:
    a. Diagnosis of systemic ALCL that is anaplastic lymphoma kinase (ALK)-positive; and
    b. Relapsed or refractory disease; ~~or~~ and

~~2. Members older than 21 years of age:~~
   ~~a. Diagnosis of systemic Anaplastic Large Cell Lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK)-positive; and~~
   ~~b. Second-line or initial palliative intent therapy and subsequent therapy.~~
3. As a single agent.

Next, the College of Pharmacy recommends the prior authorization of Sandoz pemetrexed 25mg/mL solution products (billed using J9297), based on net cost, with criteria similar to Pemfexy® (pemetrexed) (changes shown in red):

Pemfexy® (Pemetrexed; J9304) and Pemetrexed 25mg/mL Solution (J9297 - Sandoz) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed; J9305) and other preferred pemetrexed 25mg/mL solution products (J9294 - Hospira, J9296 - Accord, J9314 - Teva) that do not require prior authorization must be provided.

Lastly, the College of Pharmacy recommends the removal of criteria for Tecentriq® (atezolizumab) for a diagnosis of urothelial carcinoma based on the FDA withdrawal of the accelerated approval for this indication (changes shown in red):

~~**Tecentriq® (Atezolizumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:**~~

~~1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and~~
~~2. Progressed on or following platinum-containing chemotherapy or cisplatin ineligible members.~~

Utilization Details of Lung Cancer Medications: Calendar Year 2022

The following utilization data includes medications indicated for lung cancer; however, the data does not differentiate between lung cancer and other diagnoses, for which use may be appropriate.

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OSIMERTINIB PRODUCTS						
TAGRISSO TAB 80MG	35	7	$545,854.05	$15,595.83	5	26.87%
TAGRISSO TAB 40MG	10	1	$216,642.68	$21,664.27	10	10.67%
SUBTOTAL	**45**	**8**	**$762,496.73**	**$16,944.37**	**5.63**	**37.54%**
SOTORASIB PRODUCTS						
LUMAKRAS TAB 120MG	29	6	$537,730.41	$18,542.43	4.83	26.47%
SUBTOTAL	**29**	**6**	**$537,730.41**	**$18,542.43**	**4.83**	**26.47%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALECTINIB PRODUCTS						
ALECENSA CAP 150MG	18	3	$299,459.04	$16,636.61	6	14.74%
SUBTOTAL	**18**	**3**	**$299,459.04**	**$16,636.61**	**6**	**14.74%**
AFATINIB PRODUCTS						
GILOTRIF TAB 20MG	12	1	$125,923.56	$10,493.63	12	6.20%
SUBTOTAL	**12**	**1**	**$125,923.56**	**$10,493.63**	**12**	**6.20%**
SELPERCATINIB PRODUCTS						
RETEVMO CAP 40MG	9	1	$185,502.51	$20,611.39	9	9.13%
RETEVMO CAP 80MG	2	1	$41,222.82	$20,611.41	2	2.03%
SUBTOTAL	**11**	**2**	**$226,725.33**	**$20,611.39**	**5.5**	**11.16%**
PRALSETINIB PRODUCTS						
GAVRETO CAP 100MG	3	1	$59,495.73	$19,831.91	3	2.93%
SUBTOTAL	**3**	**1**	**$59,495.73**	**$19,831.91**	**3**	**2.93%**
ERLOTINIB PRODUCTS						
ERLOTINIB TAB 100MG	2	1	$814.82	$407.41	2	0.04%
ERLOTINIB TAB 150MG	1	1	$322.41	$322.41	1	0.02%
SUBTOTAL	**3**	**2**	**$1,137.23**	**$379.08**	**1.5**	**0.06%**
ENTRECTINIB PRODUCTS						
ROZLYTREK CAP 200MG	1	1	$18,186.99	$18,186.99	1	0.90%
SUBTOTAL	**1**	**1**	**$18,186.99**	**$18,186.99**	**1**	**0.90%**
TOTAL	**122**	**23***	**$2,031,155.02**	**$16,648.81**	**5.3**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PEMETREXED J9305	376	63	$1,321,670.96	$3,515.08	5.97
ATEZOLIZUMAB J9022	308	61	$3,029,435.40	$9,835.83	5.05
DURVALUMAB J9173	250	39	$1,974,570.57	$7,898.28	6.41
RAMUCIRUMAB J9308	76	19	$537,819.78	$7,076.58	4
LURBINECTEDIN J9223	45	10	$612,902.49	$13,620.06	4.5
TRILACICLIB J1448	14	3	$41,796.00	$2,985.43	4.67
TOTAL	**1,069**	**175**	**$7,518,195.20**	**$7,032.92**	**6.11**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 03/2023. Last accessed 03/06/2023.
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[3] U.S. FDA. FDA Approves Durvalumab for Locally Advanced or Metastatic Biliary Tract Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-locally-advanced-or-metastatic-biliary-tract-cancer. Issued 09/02/2022. Last accessed 03/06/2023.
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[6] U.S. FDA. FDA Approves Tremelimumab in Combination with Durvalumab and Platinum-Based Chemotherapy for Metastatic Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-tremelimumab-combination-durvalumab-and-platinum-based-chemotherapy-metastatic-non. Issued 11/10/2022. Last accessed 03/06/2023.
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[9] Eagle Pharmaceuticals, Inc. Eagle Pharmaceuticals Receives FDA Approval for Additional Indication for Pemfexy® in Combination with Pembrolizumab and Platinum Chemotherapy. Available online at: https://www.globenewswire.com/en/news-release/2022/12/19/2576128/0/en/Eagle-Pharmaceuticals-Receives-FDA-Approval-for-Additional-Indication-for-PEMFEXY-in-Combination-with-Pembrolizumab-and-Platinum-Chemotherapy.html. Issued 12/19/2022. Last accessed 03/06/2023.
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Appendix K

Calendar Year 2022 Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Brenzavvy™ (Bexagliflozin), Mounjaro® (Tirzepatide), and Tzield™ (Teplizumab-mzwv)

Oklahoma Health Care Authority
April 2023

Current Prior Authorization Criteria

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/ glipizide (Metaglip®)			metformin ER susp (Riomet ER™)
metformin/ glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	linagliptin/metformin ER (Jentadueto® XR)
	linagliptin/ metformin (Jentadueto®)	alogliptin/ metformin (Kazano®)	
	sitagliptin (Januvia®)	alogliptin/ pioglitazone (Oseni®)	
	sitagliptin/ metformin (Janumet®)	saxagliptin (Onglyza®)	

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	sitagliptin/ metformin ER (Janumet XR®)	saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)	
DPP-4 Inhibitors/SGLT-2 Inhibitors			
	empagliflozin/ linagliptin (Glyxambi®)	dapagliflozin/ saxagliptin (Qtern®)	
		ertugliflozin/ sitagliptin (Steglujan®)	
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GLP-1 Agonists			
	dulaglutide (Trulicity®)	semaglutide (Ozempic®)	exenatide ER autoinjector (Bydureon BCise®)
	exenatide (Byetta®)		lixisenatide (Adlyxin®)
	liraglutide (Victoza®)		semaglutide (Rybelsus®)
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)+	
		insulin glargine/ lixisenatide (Soliqua® 100/33)+	
SGLT-2 Inhibitors			
	dapagliflozin (Farxiga®)	canagliflozin (Invokana®)	canagliflozin/ metformin ER (Invokamet® XR)
	dapagliflozin/ metformin ER (Xigduo® XR)	canagliflozin/ metformin (Invokamet®)	
	empagliflozin (Jardiance®)	ertugliflozin (Steglatro®)	
	empagliflozin/ metformin (Synjardy®)	ertugliflozin/ metformin (Segluromet®)	

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	empagliflozin/ metformin ER (Synjardy® XR)		
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
	empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)		dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)
Sulfonylureas			
chlorpropamide (Diabinese®)			
glimepiride (Amaryl®)			
glipizide (Glucotrol®)			
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
tolbutamide (Orinase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	
		rosiglitazone/ glimepiride (Avandaryl®)	
		rosiglitazone/ metformin (Avandamet®)	

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
⁺Unique criteria applies.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release; susp = suspension

Anti-Diabetic Medications Tier-2 Approval Criteria:

1. A trial at least 3 months in duration (unless intolerable adverse effects) of metformin titrated up to maximum tolerated dose or a patient-specific, clinically significant reason why a 3-month trial of metformin titrated up to maximum tolerated dose is not appropriate must be provided.
2. For initiation with dual or triple therapy, additional Tier-2 medications may be approved based on current American Association of Clinical Endocrinologists (AACE) or American Diabetes Association (ADA) guidelines.
3. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 medications. Tier structure rules for unique FDA approved indications will apply.

Anti-Diabetic Medications Tier-3 Approval Criteria:

1. Member must have tried 1 Tier-2 medication in the same category and have a documented clinical reason why the Tier-2 medication is not appropriate (for Tier-3 medications that do not have a similar category in Tier-2, a medication from any category in Tier-2 may be used).
2. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications. Tier structure rules for unique FDA approved indications will apply.

Anti-Diabetic Medications Special Prior Authorization (PA) Approval Criteria:

1. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
2. Use of Invokamet® XR [canagliflozin/metformin extended-release (ER)] or Jentadueto® XR (linagliptin/metformin ER) will require a patient-specific, clinically significant reason why the member cannot take the immediate-release formulation(s); and
3. Use of Adlyxin® (lixisenatide), Bydureon BCise® (exenatide ER autoinjector pen), or Rybelsus® (semaglutide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide 1 (GLP-1) receptor agonists.

Admelog® (Insulin Lispro), Insulin Lispro U-100 (Generic Humalog U-100), and Lyumjev® U-100 (Insulin Lispro-aabc 100 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Humalog® (the brand formulation of Humalog® is preferred).

Afrezza® (Insulin Human Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus (DM); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why other rapid-acting injectable insulins are not appropriate must be provided; and
4. For the diagnosis of type 1 DM, the member must use Afrezza® with a long-acting insulin; and
5. Member must not smoke or have chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

Basaglar® (Insulin Glargine) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Levemir® (insulin detemir) must be provided.

Fiasp® (Insulin Aspart) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use NovoLog® (insulin aspart) must be provided.

Humalog® KwikPen® U-200 (Insulin Lispro 200 Units/mL) and Lyumjev® KwikPen U-200 (Insulin Lispro-aabc 200 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. Authorization of the 200 units/mL strength requires a patient-specific, clinically significant reason why the member cannot use the 100 units/mL strength (the brand formulation of Humalog® U-100 is preferred).

Humulin® R U-500 Vials (Insulin Human 500 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use the Humulin® R U-500 KwikPen® (insulin human 500 units/mL), which is available without prior authorization, must be provided.

Kerendia® (Finerenone) Approval Criteria:

1. An FDA approved indication to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and
2. Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and

3. A patient specific, clinically significant reason why the member cannot use a sodium-glucose cotransporter-2 (SGLT-2) inhibitor must be provided; and
4. Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
5. Member must not have adrenal insufficiency; and
6. Member must not have severe hepatic impairment (Child Pugh C); and
7. Prescriber must measure serum potassium and eGFR prior to initiation of Kerendia®; and
8. Prescriber must verify serum potassium is not >5.0mEq/L prior to treatment initiation with Kerendia®; and
9. Prescriber must agree to monitor serum potassium levels 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
10. Initial authorization will be for 4 weeks, after which time serum potassium levels will be required for continued approval; and
11. A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:
    a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m^2; or
    b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m^2.

Rezvoglar™ (Insulin Glargine-aglr) and Semglee® (Insulin Glargine-yfgn) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Levemir® (insulin detemir) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Ryzodeg® (Insulin Degludec/Insulin Aspart) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Levemir® (insulin detemir) with NovoLog® (insulin aspart) must be provided.

Soliqua® 100/33 (Insulin Glargine/Lixisenatide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and

2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) with an alternative glucagon-like peptide 1 (GLP-1) receptor agonist must be provided; and
3. Current Tier-3 criteria will apply.

Symlin® (Pramlintide) Approval Criteria:

1. An FDA approved diagnosis of type 1 or type 2 diabetes; and
2. Member must be using a basal-bolus insulin regimen; and
3. Member must have failed to achieve adequate glycemic control on basal-bolus insulin regimen or are gaining excessive weight on basal-bolus insulin regimen; and
4. Member must be receiving ongoing care under the guidance of a health care professional; and
5. Members meeting any of the following criteria should not be considered for Symlin® (pramlintide) therapy:
    a. Poor compliance with insulin regimen; or
    b. Poor compliance with self-blood glucose monitoring; or
    c. Hemoglobin A1C (HbA1c) >9%; or
    d. Recurrent severe hypoglycemia requiring assistance in the past 6 months; or
    e. Presence of hypoglycemia unawareness; or
    f. Diagnosis of gastroparesis; or
    g. Required use of medications that stimulate gastrointestinal motility; or
    h. Pediatric members 15 years of age or younger.

Toujeo® (Insulin Glargine) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) must be provided, and the member must be using a minimum of 100 units of Lantus® (insulin glargine) per day.

Tresiba® (Insulin Degludec) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Levemir® (insulin detemir) must be provided.

Xultophy® 100/3.6 (Insulin Degludec/Liraglutide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) with Victoza® (liraglutide) must be provided; and
3. Current Tier-3 criteria will apply.

Utilization of Anti-Diabetic Medications and Kerendia® (Finerenone): Calendar Year 2022

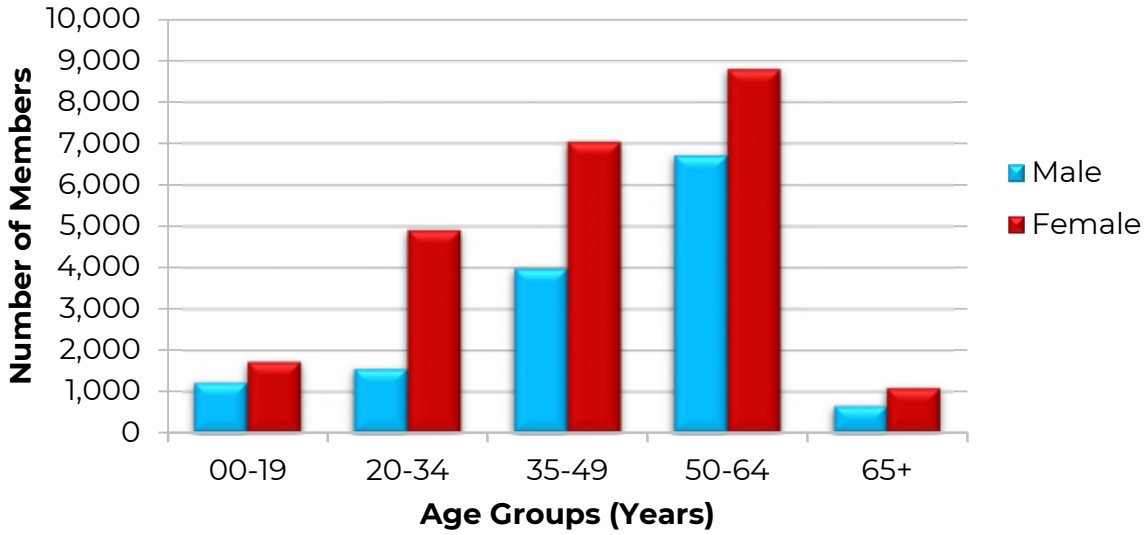
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	26,470	156,080	$64,258,580.59	$411.70	$8.73	8,833,220	7,356,483
2022	37,528	237,280	$108,584,390.54	$457.62	$9.24	13,931,138	11,752,086
% Change	**41.8%**	**52.0%**	**69.0%**	**11.2%**	**5.8%**	**57.7%**	**59.8%**
Change	**11,058**	**81,200**	**$44,325,809.95**	**$45.92**	**$0.51**	**5,097,918**	**4,395,603**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

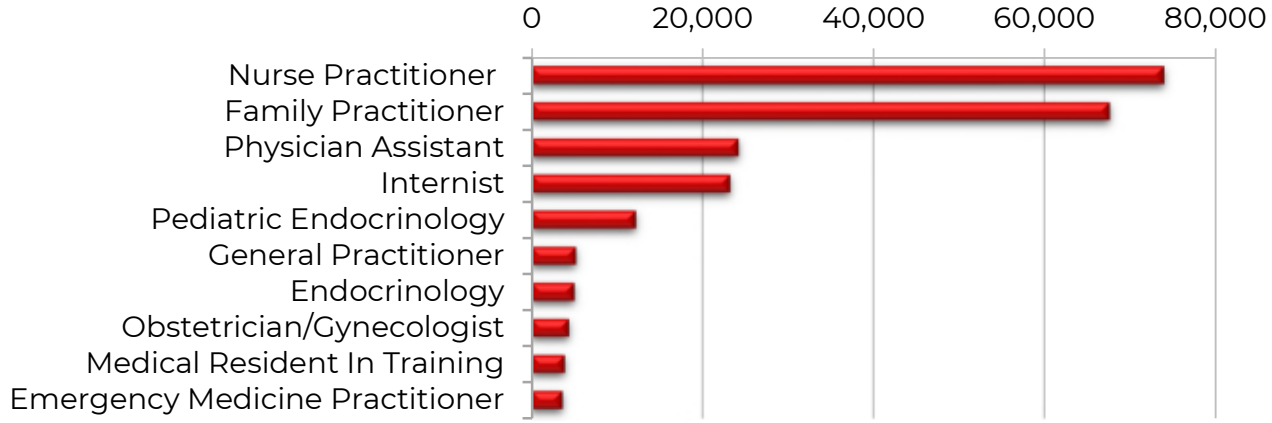
- Aggregate drug rebates collected during fiscal year 2022 (07/01/2021 to 06/30/2022) for anti-diabetic medications and Kerendia® (finerenone) totaled $82,446,823.77.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2022 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2022 are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Anti-Diabetic Medications and Kerendia® (Finerenone)



[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

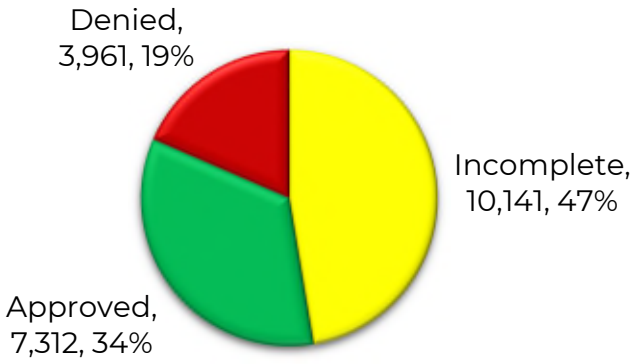
Top Prescriber Specialties of Anti-Diabetic Medications and Kerendia® (Finerenone) by Number of Claims



Prior Authorization of Anti-Diabetic Medications and Kerendia® (Finerenone)

There were 21,414 prior authorization requests submitted for anti-diabetic medications and Kerendia® during calendar year 2022. Of the 21,414 total prior authorization requests submitted, 16,558 were for non-insulin anti-diabetic medications and Kerendia® and 4,856 were for insulin products. Computer edits are in place to detect lower tiered non-insulin medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15]

Anticipated Patent Expiration(s):

- Kombiglyze® XR [saxagliptin/metformin extended-release (ER) tablet]: July 2025
- Januvia® (sitagliptin tablet): May 2027

- Janumet® XR (sitagliptin/metformin ER tablet): May 2027
- Onglyza® (saxagliptin tablet): November 2028
- Janumet® (sitagliptin/metformin tablet): January 2029
- Actoplus Met® (pioglitazone/metformin tablet): February 2029
- Invokamet® (canagliflozin/metformin tablet): February 2029
- Invokamet® XR (canagliflozin/metformin ER tablet): February 2029
- Kerendia® (finerenone tablet): April 2029
- Qtern® (dapagliflozin/saxagliptin tablet): December 2029
- Farxiga® (dapagliflozin tablet): May 2030
- Jentadueto® (linagliptin/metformin tablet): June 2030
- Steglatro® (ertugliflozin tablet): July 2030
- Bydureon BCise® (exenatide ER auto-injector): October 2030
- Steglujan® (ertugliflozin/sitagliptin tablet): October 2030
- Segluromet® (ertugliflozin/metformin tablet): October 2030
- Xigduo® XR (dapagliflozin/metformin ER tablet): November 2030
- Tradjenta® (linagliptin tablet): March 2031
- Invokana® (canagliflozin tablet): May 2031
- Cycloset® (bromocriptine tablet): April 2032
- Brenzavvy™ (bexagliflozin tablet): May 2032
- Jentadueto XR® (linagliptin/metformin ER tablet): March 2033
- Ozempic® (semaglutide injection): June 2033
- Adlyxin® (lixisenatide injection): March 2034
- Synjardy® (empagliflozin/metformin tablet): April 2034
- Rybelsus® (semaglutide tablet): May 2034
- Glyxambi® (empagliflozin/linagliptin tablet): June 2034
- Synjardy® XR (empagliflozin/metformin ER tablet): June 2034
- Trijardy® XR (empagliflozin/linagliptin/metformin ER tablet): June 2034
- Jardiance® (empagliflozin tablet): June 2034
- Riomet ER™ (metformin ER oral suspension): May 2035
- Victoza® (liraglutide injection): July 2037
- Mounjaro® (tirzepatide injection): June 2039

New U.S. Food and Drug Administration (FDA) Approval(s):

- **May 2022:** The FDA approved Mounjaro® (tirzepatide) injection to improve blood sugar control in adults with type 2 diabetes (T2DM), as an addition to diet and exercise. Mounjaro® activates both the glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) receptors leading to improved blood sugar control. Mounjaro® is administered by subcutaneous (sub-Q) injection once weekly, with the dose adjusted as tolerated.
- **November 2022:** The FDA approved Tzield™ (teplizumab-mzwv) injection to delay the onset of stage 3 type 1 diabetes (T1DM) in adults

and pediatric patients 8 years of age and older who currently have stage 2 T1DM. Tzield™ binds to certain immune system cells and delays progression to stage 3 T1DM. Tzield™ is administered by intravenous (IV) infusion once daily for 14 consecutive days.

- **January 2023:** The FDA approved Brenzavvy™ (bexagliflozin), an oral sodium-glucose cotransporter 2 (SGLT-2) inhibitor. Brenzavvy™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.

News:

- **August 2022:** A FIDELITY meta-analysis provided an overview of Kerendia® (finerenone) highlighting the specific cardioprotective benefits and all-cause risk reduction among patients with chronic kidney disease (CKD) and T2DM. Patient data was pooled from the FIDELIO-DKD and FIGARO-DKD trials, and results suggested the use of finerenone was associated with an 11% reduction in risk of all-cause mortality, including a 25% reduction in relative risk of sudden cardiac death.
- **September 2022:** Kerendia® (finerenone) received a label update that now will include findings from the FIGARO-DKD cardiovascular (CV) outcomes trial in patients with CKD and T2DM. The FIGARO-DKD trial showed that finerenone significantly reduced the risk of time to first occurrence of cardiovascular (CV) death, non-fatal myocardial infarction (MI), non-fatal stroke, or hospitalization for heart failure (HF), its primary composite endpoint. With these additions, the label now includes data of more than 13,000 patients with CKD associated with T2DM.
- **November 2022:** Rezvoglar® (insulin glargine-aglr) has been approved as an interchangeable biosimilar to Lantus® (insulin glargine). Rezvoglar® was originally FDA approved in 2021 and is now the second FDA approved interchangeable biosimilar insulin product in the United States.
- **January 2023:** The FDA accepted a supplemental New Drug Application (sNDA) for Jardiance® (empagliflozin) for a new indication to reduce the risk of kidney disease progression and CV death in adults with CKD. The sNDA is based on results from the EMPA-KIDNEY Phase 3 trial.
- **March 2023:** The FDA accepted an sNDA for Jardiance® (empagliflozin) for a new indication to lower blood sugar along with diet and exercise in children 10 years of age and older with T2DM. The sNDA is based on the results from the DINAMO Phase 3 trial, in which Jardiance® was compared to placebo to assess the change from baseline in hemoglobin A1c (HbA1c) in patients 10 to 17 years of age.

Guideline Update(s):

- **American Diabetes Association (ADA) guideline update:** The ADA released the *Standards of Medical Care in Diabetes 2023,* to include new and updated practice guidelines to care for patients with diabetes and prediabetes. Some notable updates and additions include:
  - In adults with T2DM and established/high risk of atherosclerotic CV disease (ASCVD), HF, and/or CKD, treatment plans should include agents that reduce cardiorenal risk.
  - New hypertension (HTN) diagnosis cut-offs were added and now define HTN as a systolic blood pressure (BP) ≥130mmHg or a diastolic BP ≥80mmHg. A target BP of <130/80mmHg is recommended for patients with diabetes.
  - Initiation of an SGLT-2 inhibitor can now be considered at an estimated glomerular filtration rate (eGFR) ≥20mL/min/1.73m^2 and urinary albumin ≥200mg/g creatinine.
  - The role of SGLT-2 inhibitors has been expanded in HF with preserved and reduced ejection fraction.
  - In individuals with diabetes and CKD with albuminuria who are at increased risk for CV events or CKD progression, finerenone is now recommended rather than considered an alternative option.
  - New lipid management recommendations suggest lower low-density lipoprotein (LDL) goals for high-risk individuals.
  - Emphasis was placed on supporting higher weight loss (up to 15%) based on the efficacy of and access to newer medications when appropriate.
- **Kidney Disease Improving Global Outcomes (KDIGO) 2022 Clinical Practice Guideline Update:** The KDIGO 2022 Clinical Practice Guideline for Diabetes Management in CKD has been updated to addresses both T1DM and T2DM, all stages of CKD, patients with a kidney transplant, and patients treated with hemodialysis or peritoneal dialysis. Some notable updates and additions include:
  - Patients with diabetes and CKD should be treated with a comprehensive strategy to reduce risks of kidney disease progression and CV disease (CVD).
  - Patients with T2DM, CKD, and an eGFR ≥20mL/min/1.73m^2 should be treated with SGLT-2 inhibitors. The choice of an SGLT-2 inhibitor should prioritize agents with documented kidney or CV benefits and take eGFR into account.
  - Use of a nonsteroidal mineralocorticoid receptor antagonist (MRA) with proven kidney or CV benefit is recommended for patients with T2DM, an eGFR ≥25mL/min/1.73m^2, normal serum potassium concentration, and albuminuria despite maximum tolerated dose of a renin-angiotensin system inhibitor (RASi). Nonsteroidal MRAs

are most appropriate for patients with T2DM who are at high risk of CKD progression and CV events, as demonstrated by persistent albuminuria despite other standard-of-care therapies. A nonsteroidal MRA can be added to a RASi and an SGLT-2 inhibitor for treatment of T2DM and CKD.

- In patients with T2DM and CKD who have not achieved individualized glycemic targets despite use of metformin and SGLT-2 inhibitor treatment or who are unable to use those medications, a long-acting GLP-1 receptor agonist is recommended.

Pipeline:

- **Diamyd®:** Diamyd® is an antigen-specific immunotherapy based on the protein GAD65 for the treatment of autoimmune diabetes. Clinical data has indicated that Diamyd® could have the potential to slow down the autoimmune destruction of beta cells through antigen-specific reprogramming. Diamyd® is currently in Phase 3 development.
- **Kerendia® (Finerenone):** Bayer is currently recruiting patients for 2 separate Phase 3 clinical trials, FINEARTS-HF and FIND-CKD, to assess the effectiveness of finerenone for HF and non-diabetic CKD, respectively. FINEARTS-HF is estimated to be completed in quarter 3 of 2024 and FIND-CKD in quarter 1 of 2026.

Brenzavvy™ (Bexagliflozin) Product Summary[16]

Therapeutic Class: SGLT-2 inhibitor

Indication(s): Adjunct to diet and exercise to improve glycemic control in adults with T2DM

How Supplied: 20mg oral tablets

Dosing and Administration:

- The recommended dosage is 20mg once daily.
- Renal function should be assessed prior to initiating Brenzavvy™ and as clinically indicated.
- Brenzavvy™ is not recommended if eGFR is <30mL/min/1.73m^2

Cost: The Wholesale Acquisition Cost (WAC) of Brenzavvy™ is not available at this time to allow for a cost analysis.

Mounjaro® (Tirzepatide) Product Summary[17]

Therapeutic Class: GLP-1/GIP receptor agonist

Indication(s): Adjunct to diet and exercise to improve glycemic control in adults with T2DM

How Supplied: 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, or 15mg per 0.5mL in a single-dose pen

Dosing and Administration:

- The recommended starting dosage is 2.5mg injected sub-Q once weekly. After 4 weeks, the dosage should be increased to 5mg sub-Q once weekly. If additional glycemic control is needed, dosage should be increased in 2.5mg increments after at least 4 weeks on the current dose.
- The maximum dosage is 15mg sub-Q once weekly.
- Mounjaro® should be injected sub-Q in the abdomen, thigh, or upper arm and injection sites should be rotated with each dose.

Cost Comparison: GLP-1 Agonists and GIP/GLP-1 Agonists

Product	Cost Per mL	Cost Per Month	Cost Per Year
Mounjaro® (tirzepatide inj) 15mg/0.5mL	**$491.00**	**$982.00⁺**	**$12,766.00⁺**
Ozempic® (semaglutide inj) 2mg/0.75mL	$299.85	$899.55*	$11,694.15*
Trulicity® (dulaglutide inj) 4.5mg/0.5mL	$447.40	$894.80±	$11,632.40±

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
⁺Mounjaro® cost is based on a maximum FDA recommended dose of 15mg every week.
*Ozempic® cost is based on the maximum FDA recommended dose of 2mg every week.
±Trulicity® cost is based on the maximum FDA recommended dose of 4.5mg every week.
inj = injection

Tzield™ (Teplizumab-mzwv) Product Summary[18]

Therapeutic Class: CD3-directed antibody

Indication(s): Delay the onset of stage 3 T1DM in adults and pediatric patients 8 years of age and older with stage 2 T1DM

How Supplied: 2mg/2mL solution in a single-dose vial (SDV)

Dosing and Administration:

- Tzield™ should be administered by IV infusion over a minimum of 30 minutes, using a body surface area (BSA)-based dosing, once daily for 14 consecutive days as follows:
  - Day 1: 65mcg/m^2
  - Day 2: 125mcg/m^2
  - Day 3: 250mcg/m^2
  - Day 4: 500mcg/m^2
  - Days 5 through 14: 1,030mcg/m^2
- A diagnosis of stage 2 T1DM should be confirmed by documenting at least 2 positive pancreatic islet autoantibodies in those who have dysglycemia without overt hyperglycemia using an oral glucose

tolerance test (OGTT) or alternative method if appropriate and OGTT is not available.
- In patients who meet criteria for a diagnosis of stage 2 T1DM, the patient's clinical history should be reviewed to ensure it does not suggest a diagnosis of T2DM.
- Prior to initiating Tzield™, a complete blood count (CBC) and liver function tests (LFTs) should be obtained.
- Patients should be premedicated with: (1) a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, (2) an antihistamine, and/or (3) an antiemetic before each Tzield™ dose for at least the first 5 days of the 14-day treatment course.

Cost: The WAC of Tzield™ is $6,925 per mL or $13,850 per 2mL SDV, resulting in a total cost of $193,900 for a 14-day course treatment at 1 SDV per dose, which would be adequate dosing for most patients (up to a BSA of 1.9m^2).

Recommendations

The College of Pharmacy recommends the prior authorization of Tzield™ with the following criteria (shown in red):

Tzield™ (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
    a. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies; and
        i. Documentation must be submitted with results of autoantibody testing; and
    b. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by an abnormal oral glucose tolerance test (OGTT) meeting 1 of the following:
        i. Fasting plasma glucose ≥110mg/dL and <126mg/dl; or
        ii. 2-hour plasma glucose ≥140 mg/dL and <200mg/dl; or
        iii. 30-, 60-, or 90-minute value on OGTT ≥200mg/dl; and
2. Member must be 8 years of age or older; and
3. Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and
4. Tzield™ must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. All of the following will be required for initiation of treatment:
    a. Verification that female members of reproductive potential are not pregnant and are currently using reliable contraception; and
    b. Verification that the member has no active infection(s); and

    c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
    d. Liver function tests and verification that levels are acceptable to the prescriber; and
    e. Verification that all age-appropriate vaccinations have been administered prior to treatment; and
    f. Prescriber must agree to premedicate the member for the first 5 days of dosing and as needed with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic; and
6. Tzield™ must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Tzield™ will be administered; and
    a. Tzield™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tzield™ must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Tzield™; and
7. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. A quantity limit of 28mL per 14 days will apply; and
9. Approvals will be for (1) 14-day cycle per member per lifetime.

The College of Pharmacy also recommends updating the Anti-Diabetic Medications Tier-3 approval criteria to clarify the duration of Tier-2 trials and to be more consistent with clinical practice (changes shown in red):

Anti-Diabetic Medications Tier-3 Approval Criteria:

1. Member must have ~~tried~~ a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with 1 Tier-2 medication in the same category and have a documented clinical reason why ~~the Tier-2 medication is not appropriate~~ the member cannot continue treatment with the Tier-2 medication. For intolerable adverse effects, the member must have a documented clinical reason why they cannot utilize a different Tier-2 medication in the same category, a Tier-2 medication in a different category, or provide detailed information regarding adverse effects occurring with the Tier-2 medication(s) that are not expected to occur with the requested Tier-3 medication that is in the same category. (For Tier-3 medications that do not have a similar category in Tier-2, a medication from any category in Tier-2 may be used).

2. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications. Tier structure rules for unique FDA approved indications will apply.

Finally, the College of Pharmacy recommends the following changes to the Anti-Diabetic Medications Product Based Prior Authorization (PBPA) category (changes shown in red in the following tier chart):

1. Dipeptidyl Peptidase-4 (DPP-4) Inhibitors:
    a. Moving Jentadueto XR® (linagliptin/metformin ER), Onglyza® (saxagliptin), and Kombiglyze XR® (saxagliptin/metformin ER) to Tier-2 based on net costs; and
2. DPP-4/SGLT-2 Inhibitors:
    a. Moving Glyxambi® (empagliflozin/linagliptin) to Tier-1 based on ADA guideline recommendations and net costs after supplemental rebate participation; and
    b. Moving Steglujan® (ertugliflozin/sitagliptin) and Qtern® (dapagliflozin/saxagliptin) to the Special PA Tier based on net costs; and
3. GIP/GLP-1 Agonists:
    a. Prior authorization of Mounjaro® (tirzepatide) and placement into the Special PA Tier based on net costs; and
    b. Moving Rybelsus® (semaglutide) and Bydureon BCise® (exenatide ER autoinjector) to Tier-3 based on net costs; and
4. SGLT-2 Inhibitors:
    a. Prior authorization of Brenzavvy™ (bexagliflozin) and placement into the Special PA Tier; and
    b. Moving Farxiga® (dapagliflozin) and Jardiance® (empagliflozin) to Tier-1 based on ADA guideline recommendations, additional FDA approved indications, and net costs; and
    c. Moving Steglatro® (ertugliflozin) and Segluromet® (ertugliflozin/metformin) to the Special PA Tier based on net costs; and
5. SGLT-2 Inhibitor/DPP-4 Inhibitor/Biguanides:
    a. Moving Trijardy XR® (empagliflozin/linagliptin/metformin ER) to Tier-1 based on ADA guideline recommendations and net costs after supplemental rebate participation; and
6. Sulfonylureas:
    a. Removing Diabinese® (chlorpropamide) and Orinase® (tolbutamide) due to product discontinuation; and
7. Thiazolidinediones:
    a. Removing Avandaryl® (rosiglitazone/glimepiride) and Avandamet® (rosiglitazone/metformin) due to product discontinuation.

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/ glipizide (Metaglip®)			metformin ER susp (Riomet ER™)
metformin/ glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	~~linagliptin/metformin ER (Jentadueto® XR)~~
	linagliptin/ metformin (Jentadueto®)	alogliptin/ metformin (Kazano®)	
	linagliptin/ metformin ER (Jentadueto® XR)	alogliptin/ pioglitazone (Oseni®)	
	saxagliptin (Onglyza®)	~~saxagliptin (Onglyza®)~~	
	saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)	~~saxagliptin/ metformin (Kombiglyze®; Kombiglyze XR®)~~	
	sitagliptin (Januvia®)		
	sitagliptin/ metformin (Janumet®)		
	sitagliptin/ metformin ER (Janumet XR®)		
DPP-4 Inhibitors/SGLT-2 Inhibitors			
empagliflozin/ linagliptin (Glyxambi®)	~~empagliflozin/ linagliptin (Glyxambi®)~~	~~dapagliflozin/ saxagliptin (Qtern®)~~	dapagliflozin/ saxagliptin (Qtern®)
		~~ertugliflozin/ sitagliptin (Steglujan®)~~	ertugliflozin/ sitagliptin (Steglujan®)

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GIP/GLP-1 Agonists			
	dulaglutide (Trulicity®)	exenatide ER autoinjector (Bydureon BCise®)	~~exenatide ER autoinjector (Bydureon BCise®)~~
	exenatide (Byetta®)	semaglutide (Ozempic®)	lixisenatide (Adlyxin®)
	liraglutide (Victoza®)	semaglutide (Rybelsus®)	~~semaglutide (Rybelsus®)~~
			tirzepatide (Mounjaro®)
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)+	
		insulin glargine/ lixisenatide (Soliqua® 100/33)+	
SGLT-2 Inhibitors			
dapagliflozin (Farxiga®)	~~dapagliflozin (Farxiga®)~~	canagliflozin (Invokana®)	bexagliflozin (Brenzavvy™)
empagliflozin (Jardiance®)	dapagliflozin/ metformin ER (Xigduo® XR)	canagliflozin/ metformin (Invokamet®)	canagliflozin/ metformin ER (Invokamet® XR)
	~~empagliflozin (Jardiance®)~~	~~ertugliflozin (Steglatro®)~~	ertugliflozin (Steglatro®)
	empagliflozin/ metformin (Synjardy®)	~~ertugliflozin/ metformin (Segluromet®)~~	ertugliflozin/ metformin (Segluromet®)
	empagliflozin/ metformin ER (Synjardy® XR)		
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)	~~empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)~~		dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Sulfonylureas			
~~chlorpropamide (Diabinese®)~~			
glimepiride (Amaryl®)			
glipizide (Glucotrol®)			
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
~~tolbutamide (Orinase®)~~			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	
		~~rosiglitazone/ glimepiride (Avandaryl®)~~	
		~~rosiglitazone/ metformin (Avandamet®)~~	

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
†Unique criteria applies.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GIP = glucose-dependent insulinotropic polypeptide; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release; susp = suspension

Anti-Diabetic Medications Special Prior Authorization (PA) Approval Criteria:

1. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
2. Use of Invokamet® XR [canagliflozin/metformin extended-release (ER)] ~~or Jentaduetо® XR (linagliptin/metformin ER)~~ will require a patient-

specific, clinically significant reason why the member cannot take the immediate-release formulation(s); and

3. Use of Adlyxin® (lixisenatide)~~, Bydureon BCise® (exenatide ER autoinjector pen), or Rybelsus® (semaglutide)~~ or Mounjaro® (tirzepatide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide 1 (GLP-1) receptor agonists.

Utilization Details of Non-Insulin Anti-Diabetic Medications and Kerendia® (Finerenone): Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BIGUANIDE PRODUCTS					
TIER-1 PRODUCTS					
METFORMIN TAB 500MG	31,406	11,977	$301,109.62	$9.59	2.62
METFORMIN TAB 1000MG	22,475	7,891	$229,325.19	$10.20	2.85
METFORMIN TAB 500MG ER	14,581	5,648	$157,161.05	$10.78	2.58
METFORMIN TAB 850MG	1,307	486	$13,135.40	$10.05	2.69
METFORMIN TAB 750MG ER	1,220	527	$15,021.47	$12.31	2.31
TIER-1 SUBTOTAL	**70,989**	**26,529**	**$715,752.73**	**$10.08**	**2.68**
SPECIAL PA PRODUCTS					
METFORMIN SOL 500MG/5ML	46	12	$17,363.48	$377.47	3.83
METFORMIN ER TAB 1000MG	3	1	$285.95	$95.32	3
SPECIAL PA SUBTOTAL	**49**	**13**	**$17,649.43**	**$360.19**	**3.77**
BIGUANIDE TOTAL	**71,038**	**26,542**	**$733,402.16**	**$10.32**	**2.68**
GLP-1 AGONIST PRODUCTS					
TIER-2 PRODUCTS					
TRULICITY INJ 1.5MG/0.5ML	8,053	2,573	$9,292,498.65	$1,153.92	3.13
TRULICITY INJ 0.75MG/0.5ML	7,858	2,886	$8,313,921.30	$1,058.02	2.72
VICTOZA INJ 18MG/3ML	4,756	1,245	$5,214,318.68	$1,096.37	3.82
TRULICITY INJ 3MG/0.5ML	3,324	1,190	$3,924,748.67	$1,180.73	2.79
TRULICITY INJ 4.5MG/0.5ML	1,787	532	$2,284,369.36	$1,278.33	3.36
BYETTA INJ 5MCG	27	11	$20,280.38	$751.13	2.45
BYETTA INJ 10MCG	23	6	$19,425.50	$844.59	3.83
TIER-2 SUBTOTAL	**25,828**	**8,443**	**$29,069,562.54**	**$1,125.51**	**3.06**
TIER-3 PRODUCTS					
OZEMPIC INJ 4MG/3ML	2,156	505	$1,822,097.58	$845.13	4.27
OZEMPIC INJ 2MG/1.5ML	2,025	680	$1,701,370.85	$840.18	2.98
OZEMPIC INJ 8MG/3ML	450	169	$381,539.55	$847.87	2.66
MOUNJARO INJ 2.5MG/0.5ML	273	180	$254,384.79	$931.81	1.52
MOUNJARO INJ 5MG/0.5ML	316	182	$291,906.85	$923.76	1.74
MOUNJARO INJ 7.5MG/0.5ML	62	48	$55,146.76	$889.46	1.29
MOUNJARO INJ 10MG/0.5ML	41	34	$36,324.67	$885.97	1.21

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
MOUNJARO INJ 15MG/0.5ML	9	3	$8,570.03	$952.23	3
MOUNJARO INJ 12.5MG/0.5ML	8	4	$5,895.52	$736.94	2
OZEMPIC INJ 2MG/1.5ML	2	2	$1,691.41	$845.71	1
TIER-3 SUBTOTAL	**5,342**	**1807**	**$4,558,928.01**	**$853.41**	**2.96**
SPECIAL PA PRODUCTS					
RYBELSUS TAB 14MG	126	19	$109,439.56	$868.57	6.63
RYBELSUS TAB 7MG	101	21	$87,263.50	$864.00	4.81
BYDUREON BC INJ 2MG/0.85ML	65	13	$49,356.90	$759.34	5
RYBELSUS TAB 3MG	14	6	$12,215.12	$872.51	2.33
BYDUREON PEN INJ 2MG	3	2	$2,202.01	$734.00	1.5
SPECIAL PA SUBTOTAL	**309**	**61**	**$260,477.09**	**$842.97**	**5.07**
GLP-1 AGONIST TOTAL	**31,479**	**10,311**	**$33,888,967.64**	**$1,076.56**	**3.05**
SULFONYLUREA PRODUCTS					
TIER-1 PRODUCTS					
GLIPIZIDE TAB 10MG	4,609	1,610	$51,822.81	$11.24	2.86
GLIPIZIDE TAB 5MG	3,922	1,521	$38,544.59	$9.83	2.58
GLYBURIDE TAB 5MG	2,346	749	$38,278.38	$16.32	3.13
GLIMEPIRIDE TAB 4MG	1,963	695	$22,517.63	$11.47	2.82
GLIPIZIDE ER TAB 10MG	1,816	670	$39,818.99	$21.93	2.71
GLIMEPIRIDE TAB 2MG	1,461	525	$15,467.27	$10.59	2.78
GLIPIZIDE ER TAB 5MG	1,284	519	$19,769.12	$15.40	2.47
GLIPIZIDE ER TAB 2.5MG	530	205	$8,896.57	$16.79	2.59
GLYBURIDE TAB 2.5MG	529	219	$7,751.52	$14.65	2.42
GLIMEPIRIDE TAB 1MG	505	206	$4,657.68	$9.22	2.45
GLYBURIDE TAB 1.25MG	92	30	$1,139.24	$12.38	3.07
GLIPIZIDE XL TAB 5MG	45	33	$752.92	$16.73	1.36
GLIPIZIDE XL TAB 10MG	44	26	$1,171.08	$26.62	1.69
GLYBURID MCR TAB 6MG	33	7	$649.67	$19.69	4.71
GLYBURID MCR TAB 3MG	32	8	$541.57	$16.92	4
GLIPIZIDE XL TAB 2.5MG	18	9	$295.70	$16.43	2
GLYBURID MCR TAB 1.5MG	7	4	$125.92	$17.99	1.75
SULFONYLUREA TOTAL	**19,236**	**7,036**	**$252,200.66**	**$13.11**	**2.73**
SGLT-2 INHIBITOR PRODUCTS					
TIER-2 PRODUCTS					
JARDIANCE TAB 25MG	5,693	1,846	$6,193,544.25	$1,087.92	3.08
JARDIANCE TAB 10MG	4,315	1,580	$4,105,739.03	$951.50	2.73
FARXIGA TAB 10MG	3,763	1,175	$3,496,176.86	$929.09	3.2
FARXIGA TAB 5MG	896	336	$796,277.55	$888.70	2.67
TIER-2 SUBTOTAL	**14,667**	**4,937**	**$14,591,737.69**	**$994.87**	**2.97**
TIER-3 PRODUCTS					
INVOKANA TAB 300MG	211	56	$219,437.67	$1,039.99	3.77
INVOKANA TAB 100MG	147	42	$154,217.05	$1,049.10	3.5
STEGLATRO TAB 15MG	50	8	$16,029.15	$320.58	6.25

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
STEGLATRO TAB 5MG	3	2	$968.61	$322.87	1.5
TIER-3 SUBTOTAL	**411**	**108**	**$390,652.48**	**$950.49**	**3.81**
SGLT-2 INHIBITOR TOTAL	**15,078**	**5,045**	**$14,982,390.17**	**$993.66**	**2.99**
DPP-4 INHIBITOR PRODUCTS					
TIER-2 PRODUCTS					
JANUVIA TAB 100MG	3,755	1,072	$3,589,843.09	$956.02	3.5
TRADJENTA TAB 5MG	1,952	339	$954,902.87	$489.19	5.76
JANUVIA TAB 50MG	946	282	$852,833.41	$901.52	3.35
JANUVIA TAB 25MG	349	141	$296,989.31	$850.97	2.48
TIER-2 SUBTOTAL	**7,002**	**1,834**	**$5,694,568.68**	**$813.28**	**3.82**
TIER-3 PRODUCTS					
ONGLYZA TAB 5MG	85	16	$57,248.66	$673.51	5.31
ALOGLIPTIN TAB 25MG	46	6	$8,325.11	$180.98	7.67
ALOGLIPTIN TAB 12.5MG	17	5	$3,574.89	$210.29	3.4
ONGLYZA TAB 2.5MG	9	3	$5,523.43	$613.71	3
ALOGLIPTIN TAB 6.25MG	6	1	$1,074.32	$179.05	6
TIER-3 SUBTOTAL	**163**	**31**	**$75,746.41**	**$464.70**	**5.26**
DPP-4 INHIBITOR SUBTOTAL	**7,165**	**1,865**	**$5,770,315.09**	**$805.35**	**3.84**
TZD PRODUCTS					
TIER-1 PRODUCTS					
PIOGLITAZONE TAB 30MG	2,012	732	$33,258.20	$16.53	2.75
PIOGLITAZONE TAB 15MG	1,758	659	$24,975.33	$14.21	2.67
PIOGLITAZONE TAB 45MG	1,066	352	$18,595.34	$17.44	3.03
TZD TOTAL	**4,836**	**1,743**	**$76,828.87**	**$15.89**	**2.77**
DPP-4 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS					
TIER-2 PRODUCTS					
JANUMET TAB 50-1000MG	1,060	330	$961,614.92	$907.18	3.21
JANUMET XR TAB 100-1000MG	326	82	$276,027.92	$846.71	3.98
JANUMET XR TAB 50-1000MG	310	81	$251,477.13	$811.22	3.83
JENTADUETO TAB 2.5-1000MG	253	84	$270,165.57	$1,067.85	3.01
JANUMET TAB 50-500MG	181	49	$145,266.96	$802.58	3.69
JANUMET XR TAB 50-500MG	10	5	$6,580.95	$658.10	2
JENTADUETO TAB 2.5-850MG	4	1	$4,849.91	$1,212.48	4
JENTADUETO TAB 2.5-500MG	4	2	$5,854.36	$1,463.59	2
TIER-2 SUBTOTAL	**2,148**	**634**	**$1,921,837.72**	**$894.71**	**3.39**
TIER-3 PRODUCTS					
KOMBIGLYZE XR TAB 2.5-1000MG	20	4	$7,354.99	$367.75	5
KOMBIGLYZE XR TAB 5-1000MG	5	1	$5,909.93	$1,181.99	5
OSENI TAB 25-30MG	3	1	$3,703.41	$1,234.47	3
TIER-3 SUBTOTAL	**28**	**6**	**$16,968.33**	**$606.01**	**4.67**
SPECIAL PA PRODUCTS					
JENTADUETO XR TAB 5-1000MG	4	1	$3,915.40	$978.85	4
JENTADUETO XR TAB 2.5-1000MG	1	1	$496.19	$496.19	1

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SPECIAL PA SUBTOTAL	**5**	**2**	**$4,411.59**	**$882.32**	**2.5**
DPP-4 INHIBITOR/BIGUANIDE COMBINATION TOTAL	**2,181**	**642**	**$1,943,217.64**	**$890.98**	**3.4**
SGLT-2 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS					
TIER-2 PRODUCTS					
SYNJARDY XR TAB 25-1000MG	317	106	$337,827.85	$1,065.70	2.99
SYNJARDY TAB 12.5-1000MG	312	94	$269,279.67	$863.08	3.32
XIGDUO XR TAB 10-1000MG	263	66	$243,566.20	$926.11	3.98
XIGDUO XR TAB 5-1000MG	138	48	$125,889.02	$912.24	2.88
SYNJARDY TAB 5-1000MG	102	40	$110,388.16	$1,082.24	2.55
SYNJARDY XR TAB 12.5-1000MG	85	33	$53,231.22	$626.25	2.58
SYNJARDY XR TAB 10-1000MG	61	22	$60,204.16	$986.95	2.77
XIGDUO XR TAB 10-500MG	29	9	$24,578.70	$847.54	3.22
XIGDUO XR TAB 2.5-1000MG	29	5	$13,606.74	$469.20	5.8
SYNJARDY TAB 12.5-500MG	21	7	$16,587.47	$789.88	3
SYNJARDY XR TAB 5-1000MG	19	9	$10,849.27	$571.01	2.11
SYNJARDY TAB 5-500MG	14	4	$15,346.20	$1,096.16	3.5
XIGDUO XR TAB 5-500MG	11	3	$9,047.35	$822.49	3.67
TIER-2 SUBTOTAL	**1,401**	**446**	**$1,290,402.01**	**$921.06**	**3.14**
TIER-3 PRODUCTS					
INVOKAMET TAB 150-1000MG	29	5	$21,434.25	$739.11	5.8
SEGLUROMET TAB 7.5-1000MG	19	2	$5,679.83	$298.94	9.5
SEGLUROMET TAB 2.5-1000MG	11	1	$1,798.98	$163.54	11
INVOKAMET TAB 50-1000MG	6	1	$3,350.28	$558.38	6
INVOKAMET TAB 50-500MG	3	1	$5,164.77	$1,721.59	3
SEGLUROMET TAB 2.5-500MG	1	1	$336.01	$336.01	1
TIER-3 SUBTOTAL	**69**	**11**	**$37,764.12**	**$547.31**	**6.27**
SPECIAL PA PRODUCTS					
INVOKAMET XR TAB 150-1000MG	8	1	$5,484.93	$685.62	8
INVOKAMET XR TAB 50-1000MG	4	1	$6,597.44	$1,649.36	4
SPECIAL PA SUBTOTAL	**12**	**2**	**$12,082.37**	**$1,006.86**	**6**
SGLT-2 INHIBITOR/BIGUANIDE COMBINATION TOTAL	**1,482**	**459**	**$1,340,248.50**	**$904.35**	**3.23**
SULFONYLUREA/BIGUANIDE COMBINATION PRODUCTS					
TIER-1 PRODUCTS					
GLYB/METFORMIN TAB 5-500MG	208	56	$3,447.95	$16.58	3.71
GLIP/METFORMIN TAB 5-500MG	116	41	$4,622.38	$39.85	2.83
GLYB/METFORMIN TAB 2.5-500MG	81	29	$1,260.64	$15.56	2.79
GLIP/METFORMIN TAB 2.5-500MG	36	25	$1,599.80	$44.44	1.44
GLIP/METFORMIN TAB 2.5-250MG	5	2	$176.85	$35.37	2.5
GLYB/METFORMIN TAB 1.25-250MG	3	1	$82.17	$27.39	3
SULFONYLUREA/BIGUANIDE COMBINATION TOTAL	**449**	**154**	**$11,189.79**	**$24.92**	**2.92**
SGLT-2 INHIBITOR/DPP-4 INHIBITOR COMBINATION PRODUCTS					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-2 PRODUCTS					
GLYXAMBI TAB 25-5 MG	211	35	$111,424.61	$528.08	6.03
GLYXAMBI TAB 10-5 MG	112	17	$57,022.65	$509.13	6.59
TIER-2 SUBTOTAL	**323**	**52**	**$168,447.26**	**$521.51**	**6.21**
TIER-3 PRODUCTS					
STEGLUJAN TAB 5-100MG	18	2	$9,740.91	$541.16	9
STEGLUJAN TAB 15-100MG	5	1	$2,687.35	$537.47	5
TIER-3 SUBTOTAL	**23**	**3**	**$12,428.26**	**$540.36**	**7.67**
SGLT-2/DPP-4 INHIBITOR COMBINATION TOTAL	**346**	**55**	**$180,875.52**	**$522.76**	**6.29**
ALPHA-GLUCOSIDASE INHIBITOR PRODUCTS					
TIER-1 PRODUCTS					
ACARBOSE TAB 25MG	169	60	$4,479.28	$26.50	2.82
ACARBOSE TAB 50MG	55	16	$1,444.10	$26.26	3.44
ACARBOSE TAB 100MG	52	13	$1,808.30	$34.78	4
ALPHA-GLUCOSIDASE INHIBITOR TOTAL	**276**	**89**	**$7,731.68**	**$28.01**	**3.1**
GLP-1 AGONIST/INSULIN COMBINATION PRODUCTS					
TIER-3 PRODUCTS					
SOLIQUA INJ 100U/33MCG	176	29	$130,564.98	$741.85	6.07
XULTOPHY INJ 100U/3.6MG	44	8	$47,004.82	$1,068.29	5.5
GLP-1 AGONIST/INSULIN COMBINATION TOTAL	**220**	**37**	**$177,569.80**	**$807.14**	**5.95**
GLINIDE PRODUCTS					
TIER-1 PRODUCTS					
REPAGLINIDE TAB 1MG	51	13	$1,359.26	$26.65	3.92
REPAGLINIDE TAB 2MG	23	7	$519.35	$22.58	3.29
REPAGLINIDE TAB 0.5MG	5	2	$87.10	$17.42	2.5
TIER-1 SUBTOTAL	**79**	**22**	**$1,965.71**	**$24.88**	**3.59**
TIER-2 PRODUCTS					
NATEGLINIDE TAB 120MG	31	13	$1,167.16	$37.65	2.38
NATEGLINIDE TAB 60MG	25	10	$1,165.19	$46.61	2.5
TIER-2 SUBTOTAL	**56**	**23**	**$2,332.35**	**$41.65**	**2.43**
GLINIDE TOTAL	**135**	**45**	**$4,298.06**	**$31.84**	**3**
SGLT-2/DPP-4 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS					
TRIJARDY XR TAB 25-5-1000MG	110	24	$60,900.45	$553.64	4.58
TRIJARDY XR TAB 12.5-2.5-1000MG	10	2	$5,595.00	$559.50	5
TRIJARDY XR TAB 5-2.5-1000MG	7	1	$1,982.05	$283.15	7
TRIJARDY XR TAB 10-5-1000MG	5	3	$2,772.67	$554.53	1.67
SGLT-2/DPP-4/BIGUANIDE COMBINATION TOTAL	**132**	**30**	**$71,250.17**	**$539.77**	**4.4**
TZD/BIGUANIDE COMBINATION PRODUCTS					
TIER-3 PRODUCTS					
PIOG/METFORMIN TAB 15-850MG	56	6	$1,758.85	$31.41	9.33

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PIOG/METFORMIN TAB 15-500MG	5	2	$253.22	$50.64	2.5
TZD/BIGUANIDE COMBINATION TOTAL	**61**	**8**	**$2,012.07**	**$32.98**	**7.63**
DPP-4 INHIBITOR/TZD COMBINATION PRODUCTS					
TIER-3 PRODUCTS					
ALOG/PIOG TAB 25-45MG	3	1	$1,777.23	$592.41	3
ALOG/PIOG TAB 25-30MG	1	1	$592.41	$592.41	1
DPP-4 INHIBITOR/TZD COMBINATION TOTAL	**4**	**2**	**$2,369.64**	**$592.41**	**2**
FINERENONE PRODUCTS					
KERENDIA TAB 10MG	8	2	$4,663.92	$582.99	4
KERENDIA TAB 20MG	1	1	$583.81	$583.81	1
FINERENONE TOTAL	**9**	**3**	**$5,247.73**	**$583.08**	**3**
TOTAL	**154,127**	**30,805***	**$59,450,115.19**	**$385.72**	**5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members
ALOG = alogliptin; DPP-4 = dipeptidyl peptidase-4; ER, XL, XR = extended-release; GIP = glucose-dependent insulinotropic polypeptide; GLIP = glipizide; GLP-1 = glucagon-like peptide 1; GLYB = glyburide; INJ = injection; MCR = micronized; MET = metformin; PIOG = pioglitazone; SGLT-2 = sodium-glucose cotransporter-2; SOL = solution; TZD = thiazolidinedione; TAB = tablet; U = unit

Utilization Details of Insulin Medications: Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
INSULIN GLARGINE PRODUCTS					
LANTUS SOLOSTAR INJ 100/ML	24,161	7,100	$14,150,148.35	$585.66	3.4
LANTUS INJ 100/ML	4,949	1,427	$2,579,124.94	$521.14	3.47
INSULIN GLAR INJ 100U/ML	395	282	$89,224.92	$225.89	1.4
TOUJEO MAX INJ 300U/ML	395	76	$387,154.00	$980.14	5.2
TOUJEO SOLO INJ 300U/ML	340	68	$258,083.65	$759.07	5
INSULIN GLAR INJ 100U/ML	279	149	$40,069.10	$143.62	1.87
BASAGLAR INJ 100 UNIT	134	42	$52,323.30	$390.47	3.19
INSULIN GLAR SOL 100U/ML	40	24	$6,517.03	$162.93	1.67
SEMGLEE SOL 100U/ML	26	13	$3,311.49	$127.37	2
SEMGLEE INJ 100U/ML	19	4	$2,894.31	$152.33	4.75
SEMGLEE INJ 100U/ML	18	11	$2,546.68	$141.48	1.64
INSULIN GLAR SOL 100U/ML	6	4	$1,306.57	$217.76	1.5
SUBTOTAL	**30,762**	**9,200**	**$17,572,704.34**	**$571.25**	**3.34**
INSULIN ASPART PRODUCTS					
NOVOLOG INJ FLEXPEN	5,610	1,998	$4,348,661.31	$775.16	2.81
INSULIN ASP INJ FLEXPEN	4,207	1,614	$1,640,169.51	$389.87	2.61
NOVOLOG INJ 100U/ML	2,978	729	$2,162,722.13	$726.23	4.09
NOVOLOG INJ FLEX RELION	2,230	910	$272,964.90	$122.41	2.45
INSULIN ASPA INJ 100U/ML	1,764	525	$719,299.29	$407.77	3.36
NOVOLOG INJ RELION	558	198	$115,950.94	$207.80	2.82

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
NOVOLOG INJ PENFILL	323	88	$216,294.46	$669.64	3.67
FIASP FLEX INJ TOUCH	255	50	$183,447.53	$719.40	5.1
INSULIN ASP INJ PENFILL	111	33	$43,701.88	$393.71	3.36
FIASP INJ 100U/ML	35	8	$13,911.89	$397.48	4.38
FIASP PENFILL INJ U-100	26	9	$11,442.58	$440.10	2.89
SUBTOTAL	**18,097**	**6,162**	**$9,728,566.42**	**$537.58**	**2.94**
INSULIN LISPRO PRODUCTS					
HUMALOG KWIK INJ 100U/ML	7,192	2,309	$5,409,190.56	$752.11	3.11
HUMALOG INJ 100U/ML	4,098	997	$2,830,108.13	$690.61	4.11
HUMALOG JR INJ 100U/ML	711	180	$406,826.31	$572.19	3.95
HUMALOG KWIK INJ 200U/ML	434	60	$754,438.51	$1,738.34	7.23
INSULIN LISP INJ JUNIOR	310	98	$65,565.24	$211.50	3.16
HUMALOG INJ 100U/ML	212	61	$175,851.63	$829.49	3.48
LYUMJEV KWIK INJ 100U/ML	14	5	$11,296.70	$806.91	2.8
INSULIN LISP INJ 100U/ML	5	3	$2,494.45	$498.89	1.67
LYUMJEV INJ 100U/ML	5	4	$9,220.36	$1,844.07	1.25
INSULIN LISP INJ 100U/ML	2	1	$1,125.58	$562.79	2
ADMELOG SOLO INJ 100U/ML	1	1	$200.76	$200.76	1
SUBTOTAL	**12,984**	**3,719**	**$9,666,318.23**	**$744.48**	**3.49**
INSULIN DETEMIR PRODUCTS					
LEVEMIR INJ FLEXTOUCH	9,318	2,903	$5,861,098.98	$629.01	3.21
LEVEMIR INJ	2,272	691	$1,236,950.22	$544.43	3.29
SUBTOTAL	**11,590**	**3,594**	**$7,098,049.20**	**$612.43**	**3.22**
INSULIN DEGLUDEC PRODUCTS					
TRESIBA FLEX INJ 200 UNIT	1,400	314	$1,220,842.16	$872.03	4.46
TRESIBA FLEX INJ 100 UNIT	1,242	337	$664,308.42	$534.87	3.69
TRESIBA INJ 100 UNIT	19	7	$13,224.39	$696.02	2.71
INS DEGLUDEC FLEX INJ 100 UNIT	1	1	$189.36	$189.36	1
SUBTOTAL	**2,662**	**659**	**$1,898,564.33**	**$713.21**	**4.04**
REGULAR INSULIN PRODUCTS					
HUMULIN R INJ U-100	615	205	$172,330.40	$280.21	3
HUMULIN R INJ U-500	440	95	$600,645.89	$1,365.10	4.63
NOVOLIN R INJ U-100	378	129	$93,415.00	$247.13	2.93
NOVOLIN R INJ RELION	363	119	$29,932.32	$82.46	3.05
NOVOLIN R INJ 100 UNIT	284	119	$85,996.57	$302.80	2.39
HUMULIN R INJ U-500	36	9	$49,430.69	$1,373.07	4
SUBTOTAL	**2,116**	**676**	**$1,031,750.87**	**$487.59**	**3.13**
REGULAR/NPH INSULIN COMBINATION PRODUCTS					
NOVOLIN INJ 70/30 FLEX	417	119	$128,617.06	$308.43	3.5
NOVOLIN 70/30 INJ RELION	399	121	$37,578.93	$94.18	3.3
HUMULIN INJ 70/30	334	104	$110,615.01	$331.18	3.21
NOVOLIN INJ 70/30	328	119	$122,825.49	$374.47	2.76
HUMULIN INJ 70/30 KWIK	281	83	$245,554.05	$873.86	3.39

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**1,759**	**546**	**$645,190.54**	**$366.79**	**3.22**
NPH INSULIN PRODUCTS					
HUMULIN N INJ U-100	383	144	$116,291.80	$303.63	2.66
NOVOLIN N INJ U-100	341	101	$90,515.19	$265.44	3.38
HUMULIN N INJ U-100 KWIK	298	146	$159,150.03	$534.06	2.04
NOVOLIN N INJ 100 UNIT	289	136	$50,190.03	$173.67	2.13
NOVOLIN N INJ RELION	267	89	$16,252.60	$60.87	3
SUBTOTAL	**1,578**	**616**	**$432,399.65**	**$274.02**	**2.56**
INSULIN ASPART/NPH COMBINATON PRODUCTS					
NOVOLOG MIX INJ FLEXPEN	365	119	$328,491.07	$899.98	3.07
NOVOLOG MIX INJ FLEX RELION	211	78	$31,932.41	$151.34	2.71
INS ASP PROT INJ FLEXPEN	210	66	$102,685.52	$488.98	3.18
NOVOLOG MIX INJ 70/30	92	30	$73,967.13	$803.99	3.07
NOVOLOG RELION INJ 70/30	52	20	$7,852.92	$151.02	2.6
INSULIN ASPART INJ 70/30	41	18	$12,829.29	$312.91	2.28
SUBTOTAL	**971**	**331**	**$557,758.34**	**$574.42**	**2.93**
INSULIN GLULISINE PRODUCTS					
APIDRA INJ SOLOSTAR	378	119	$303,985.13	$804.19	3.18
APIDRA INJ U-100	76	21	$48,021.94	$631.87	3.62
SUBTOTAL	**454**	**140**	**$352,007.07**	**$775.35**	**3.24**
INSULIN LISPRO/NPH COMBINATION PRODUCTS					
HUMALOG MIX INJ 75/25 KWIK	81	29	$104,044.12	$1,284.50	2.79
HUMALOG MIX SUS 75/25	55	9	$30,295.91	$550.83	6.11
INSULIN LISP INJ PROT	21	8	$3,995.87	$190.28	2.63
HUMALOG MIX INJ 50/50 KWIK	20	9	$11,785.64	$589.28	2.22
HUMALOG MIX INJ 50/50	3	2	$844.82	$281.61	1.5
SUBTOTAL	**180**	**57**	**$150,966.36**	**$838.70**	**3.16**
TOTAL	**83,153**	**14,016***	**$49,134,275.35**	**$590.89**	**5.93**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ASP = aspart; FLEX = FlexPen; GLAR = glargine; INJ = injection; INS = insulin; JR = junior; KWIK = KwikPen; LISP = lispro; POW = powder; PROT = protamine; SOL = solution; SUS = suspension; U = unit

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Appendix L

30-Day Notice to Prior Authorize Syfovre™ (Pegcetacoplan)

Oklahoma Health Care Authority
April 2023

Introduction[1,2,3,4,5,6,7]

Age-related macular degeneration (AMD) is a disorder of the eye that damages the macula, the part of the eye that controls central vision. There are 2 types of AMD: dry and wet. The majority of people with AMD have dry AMD (also called non-neovascular or atrophic AMD). Dry AMD progresses in 3 stages: early, intermediate, and advanced AMD, is slowly progressive, and can cause irreversible vision loss. In early or intermediate stages of AMD, there is a buildup of debris in the eye's retina called drusen, which is made up of proteins and fats. Geographic atrophy (GA) occurs when the buildup of drusen causes an overactivation of the immune system in the eye, which leads to inflammation damaging and destroying healthy cells in the retina. GA is characterized by well-demarcated zones of retinal cell death (also called lesions), and in the advanced stage, the foveal center is involved. GA occurs in the intermediate or advanced stages of dry AMD and is the severe form of dry AMD. Wet AMD (also called exudative or neovascular AMD), is the less common form but can cause faster vision loss. Wet AMD occurs when abnormal blood vessels cause fluid and blood to leak in the eye, damaging the macula. Any stage of dry AMD can turn into wet AMD, but wet AMD is always in the advanced stage.

AMD is the leading cause of severe, irreversible vision impairment in developed countries. In 2019, the Centers for Disease Control and Prevention (CDC) estimated 19.8 million (12.6%) Americans older than 40 years of age were living with AMD. Of these, 1.49 million (0.94%) were living with advanced AMD. The main risk factors for development of advanced AMD are increasing age, family history, smoking, low dietary antioxidants, high cholesterol, high body mass index (BMI), and increased sunlight exposure. The treatment of AMD depends on the stage and type of AMD. There is currently no treatment for early AMD. For intermediate AMD, antioxidant vitamin and mineral supplementation as per the Age-Related Eye Disease Study (AREDS2) is recommended to prevent the progression of the disease to later stages. In patients with wet AMD, anti-vascular endothelial growth factor (anti-VEGF) agents are recommended as first line treatment.

In February 2023, the U.S. Food and Drug Administration (FDA) approved Syfovre™ (pegcetacoplan) for the treatment of GA secondary to AMD.

Syfovre™ is the first and only FDA approved treatment for GA. The focus of treatment with Syfovre™ is to preserve the retina. Syfovre™ regulates complement activation, the immune process that is thought to lead to retinal cell death and the development of the GA lesions. The approval of Syfovre™ is based on positive results from the Phase 3 OAKS and DERBY studies which showed both monthly and every other month (EOM) injections of Syfovre™ reduced the rate of GA lesion growth through 24 months compared to sham.

Syfovre™ (Pegcetacoplan) Product Summary[8]

Indication(s): Syfovre™ (pegcetacoplan) is complement inhibitor indicated for the treatment of GA secondary to AMD.

How Supplied: 150mg/mL solution in a 0.1mL single dose vial (SDV) for injection

Dosing and Administration: The recommended dose of Syfovre™ is 15mg (0.1mL of solution) administered by intravitreal injection to each affected eye once every 25 to 60 days.

Cost: The Wholesale Acquisition Cost (WAC) of Syfovre™ is $2,190 per vial. The annual cost per eye will range from $13,140 to $30,660 per year, depending on injection frequency.

Recommendations

The College of Pharmacy recommends the prior authorization of Syfovre™ (pegcetacoplan) with the following criteria (shown in red):

Syfovre™ (Pegcetacoplan) Approval Criteria:

1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and
2. Member must not have ocular or periocular infections or active intraocular inflammation; and
3. Syfovre™ must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, intraocular inflammation, and neovascular (wet) AMD; and
5. A quantity limit of (1) 0.1mL single-dose vial per eye every 25 to 60 days will apply.

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Appendix M

30-Day Notice to Prior Authorize Skyclarys™ (Omaveloxolone)

Oklahoma Health Care Authority
April 2023

Introduction[1,2,3,4,5]

Friedreich's ataxia (FRDA) is a rare, genetic, autosomal recessive neurodegenerative movement disorder that is characterized by slowly progressive ataxia. FRDA is caused by mutations in the frataxin (*FXN*) gene, which encodes frataxin, a protein needed for proper functioning of the mitochondria. Mutations in the *FXN* gene lead to impaired transcription and frataxin deficiency, and the tissues that are reliant on cellular energy production begin to degenerate. Patients with FRDA primarily have ataxia, which worsens over time, and this can lead to unsteady posture, frequent falling, difficulty in walking, slurred speech, characteristic foot deformities, and scoliosis. FRDA is often associated with cardiomyopathy or irregularities in heart rhythm and up to a third of all patients with FRDA will develop diabetes mellitus.

The onset of symptoms of FRDA is typically between 5 to 15 years of age; however, patients have been diagnosed ranging from 2 to 50 years of age. FRDA also includes atypical presentations including late-onset Friedreich's ataxia (LOFA), when symptoms develop between 26 and 39 years of age, very late-onset Friedreich's ataxia (VLOFA), when symptoms occur after 40 years of age, and FRDA with retained reflexes (FARR). LOFA and VLOFA usually progress more slowly than typical FRDA and affect about 15% of patients, while FARR affects 12%. Although rare, FRDA is one of the most common hereditary ataxias and the overall prevalence is approximately 1 in 40,000 to 50,000 people in the United States.

FRDA is typically suspected based on clinical examination of the individual patients, but diagnosis is then confirmed by genetic testing to look for mutations in the *FXN* gene, with the most common (96%) type of mutation being an abnormally expanded homozygous guanine–adenine–adenine (GAA) triplet repeat expansion in intron 1 of the *FXN* gene.

Treatment of FRDA has historically been symptom-based and supportive and often includes pharmacologic, physical, occupational, speech therapies, correction of spinal and foot deformities, corrective devices for vision and hearing impairments and prostheses, walking aids, or wheelchairs for the loss of muscle coordination. In February 2023, the U.S. Food and Drug Administration (FDA) approved Skyclarys™ (omaveloxolone) for the

treatment of FRDA in adults and adolescents 16 years of age and older, making it the first therapy to be approved specifically for FRDA.

Skyclarys™ (Omaveloxolone) Product Summary[6]

Therapeutic Class: Nuclear factor-like 2 (Nrf2) activator

Indication(s): Treatment of FRDA in adults and adolescents 16 years of age and older

How Supplied: 50mg oral capsule

Dosing and Administration:

- The recommended dosage is 150mg [(3) 50mg capsules] taken orally once daily.
- Skyclarys™ should be administered on an empty stomach at least 1 hour before eating and should be swallowed whole.
- Alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, B-type natriuretic peptide (BNP), and lipid parameters should be obtained prior to initiating Skyclarys™ and during treatment.
- The dosage of Skyclarys™ should be reduced to 100mg once daily for patients with moderate hepatic impairment. If adverse reactions emerge, the dose should be reduced to 50mg once daily. Use should be avoided in patients with severe hepatic impairment.

Cost: The Wholesale Acquisition Cost of Skyclarys™ is $342.59 per capsule. This results in an estimated cost of $30,833.10 per month and $369,997.20 per year based on the recommended dose of 150mg (3 capsules) once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Skyclarys™ (omaveloxolone) with the following criteria (shown in red):

Skyclarys™ (Omaveloxolone) Approval Criteria:

1. An FDA approved diagnosis of Friedrich's ataxia (FRDA); and
    a. Diagnosis must be confirmed by genetic testing identifying a mutation in the FXN gene; and
2. Member must be 16 years of age or older; and
3. Skyclarys™ must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Member must have a left ventricular ejection fraction of ≥40%; and
5. Member must not be taking concomitant strong or moderate CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) or the prescriber must verify the dose of Skyclarys™ will be adjusted during concomitant use according to package labeling; and

6. Member must not be taking concurrent strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); and
7. Member must not have severe hepatic impairment (Child-Pugh class C); and
8. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Skyclarys™ treatment, every month for the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
9. Prescriber must verify that B-type natriuretic peptide (BNP) will be assessed prior to initiation of Skyclarys™ and cardiac function will be monitored as clinically indicated; and
10. Prescriber must verify lipid parameters will be monitored prior to initiation of Skyclarys™ treatment and periodically thereafter or as clinically indicated; and
11. Female members must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective non-hormonal contraception during therapy and for 28 days after discontinuation of therapy; and
12. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document that the member is responding to the medication, as indicated by slower disease progression and/or other documentation of a positive clinical response to therapy; and
13. A quantity limit of 90 capsules per 30 days will apply.

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[1] National Organization for Rare Disorders (NORD). Friedreich's Ataxia. Available online at: https://rarediseases.org/rare-diseases/friedreichs-ataxia/. Last revised 03/15/2023. Last accessed 03/20/2023.
[2] Bidichandani S, Delatycki M. Friedreich's Ataxia. *GeneReviews®*. Available online at: https://www.ncbi.nlm.nih.gov/books/NBK1281/. Last revised 06/01/2017. Last accessed 03/20/2023.
[3] Genetic and Rare Diseases (GARD) Information Center. Friedreich's Ataxia. Available online at: https://rarediseases.info.nih.gov/diseases/6468/friedreich-ataxia. Last revised 02/2023. Last accessed 03/20/2023.
[4] George J. First Treatment Approved for Rare Neurodegenerative Disorder. *Medpage Today*. Available online at: https://www.medpagetoday.com/neurology/generalneurology/103338. Issued 03/01/2023. Last accessed 03/20/2023.
[5] Reata Pharmaceuticals. Reata Pharmaceuticals Announces FDA Approval of Skyclarys™ (Omaveloxolone), the First and Only Drug Indicated for Patients with Friedreich's Ataxia. Available online at: https://www.reatapharma.com/investors/news/news-details/2023/Reata-Pharmaceuticals-Announces-FDA-Approval-of-SKYCLARYS-Omaveloxolone-the-First-and-Only-Drug-Indicated-for-Patients-with-Friedreichs-Ataxia/default.aspx. Issued 02/28/2023. Last accessed 03/20/2023.
[6] Skyclarys™ (Omaveloxolone) Prescribing Information. Reata Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216718Orig1s000lbl.pdf. Last revised 02/2023. Last accessed 03/20/2023.

Appendix N

Calendar Year 2022 Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Ancobon® (Flucytosine) and Vivjoa® (Oteseconazole)

Oklahoma Health Care Authority
April 2023

Current Prior Authorization Criteria

Brexafemme® (Ibrexafungerp) Approval Criteria:

1. An FDA approved diagnosis of vulvovaginal candidiasis (VVC); and
2. Member must be an adult female or a post-menarchal pediatric female; and
3. Prescriber must verify that female members are not pregnant and are currently using reliable contraception; and
4. Member must not be taking concurrent strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); and
5. Authorization consideration requires a patient-specific, clinically significant reason why oral fluconazole and all topical antifungals [prescription and over-the-counter (OTC)] FDA approved for the treatment of VVC are not appropriate for the member; and
6. A quantity limit for 4 tablets for 1 day will apply.

Cresemba® (Isavuconazonium Sulfate) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Invasive aspergillosis; or
   b. Invasive mucormycosis; and
2. For the treatment of invasive aspergillosis, a patient-specific, clinically significant reason why voriconazole cannot be used must be provided.

Ketoconazole Oral Tablets Approval Criteria:

1. An FDA approved indication of systemic fungal infections with 1 of the following:
   a. Blastomycosis; or
   b. Coccidioidomycosis; or
   c. Histoplasmosis; or
   d. Chromomycosis; or
   e. Paracoccidioidomycosis; and
2. Member is 3 years of age or older; and
3. Member does not have underlying hepatic disease; and

4. Trials with other effective oral antifungal therapies, including fluconazole, itraconazole, and voriconazole, have failed to resolve infection; or
5. Other effective oral antifungal therapies are not tolerated or potential benefits outweigh the potential risks; and
6. Hepatic function tests must be done at baseline and weekly during treatment; and
7. A clinical exception may apply for members with a diagnosis of Cushing's disease when other modalities are not available.

Noxafil® (Posaconazole) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Prophylaxis of invasive *Aspergillus* and *Candida* infections in high-risk patients due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy with product use as follows:
        i. Delayed-release (DR) tablets: Adults and pediatric members 2 years of age and older who weigh >40kg; or
        ii. Intravenous (IV) injection: Adults and pediatric members 2 years of age and older; or
        iii. Oral suspension: Adults and pediatric members 13 years of age and older; or
        iv. PowderMix for DR oral suspension: Pediatric members 2 years of age and older who weigh ≤40kg; or
    b. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults and pediatric members 13 years of age and older with product use as follows:
        i. For the treatment of OPC, including rOPC to itraconazole and/or fluconazole, only the oral suspension may be used; or
    c. Treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older with product use as follows:
        i. For the treatment of invasive aspergillosis only the IV injection or DR tablets may be used; or
2. Treatment of invasive mucormycosis; or
3. Other appropriate diagnoses for which Noxafil® is not FDA approved may be considered with submission of a manual prior authorization.

Oravig® (Miconazole Buccal Tablets) Approval Criteria:

1. An FDA approved diagnosis of oropharyngeal candidiasis in adult members 18 years of age and older; and

2. Recent trials (within the last month) of the following medications at the recommended dosing and duration of therapy:
   a. Clotrimazole troches; and
   b. Nystatin suspension; and
   c. Fluconazole tablets; or
3. Contraindication(s) to all available alternative medications.

Tolsura® (Itraconazole Oral Capsules) Approval Criteria:

1. An FDA approved indication of 1 of the following fungal infections in immunocompromised and non-immunocompromised adult members:
   a. Blastomycosis, pulmonary and extrapulmonary; or
   b. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; or
   c. Aspergillosis, pulmonary and extrapulmonary, in members who are intolerant of or who are refractory to amphotericin B therapy; and
2. A patient-specific, clinically significant reason why the member cannot use itraconazole 100mg capsules, which are available without prior authorization, must be provided.

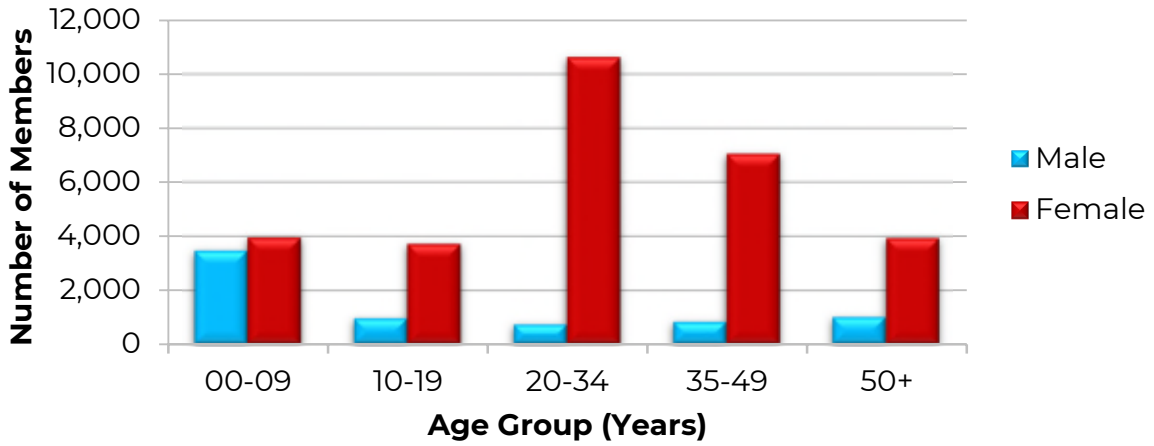
Utilization of Systemic Antifungal Medications: Calendar Year 2022

Comparison of Calendar Years

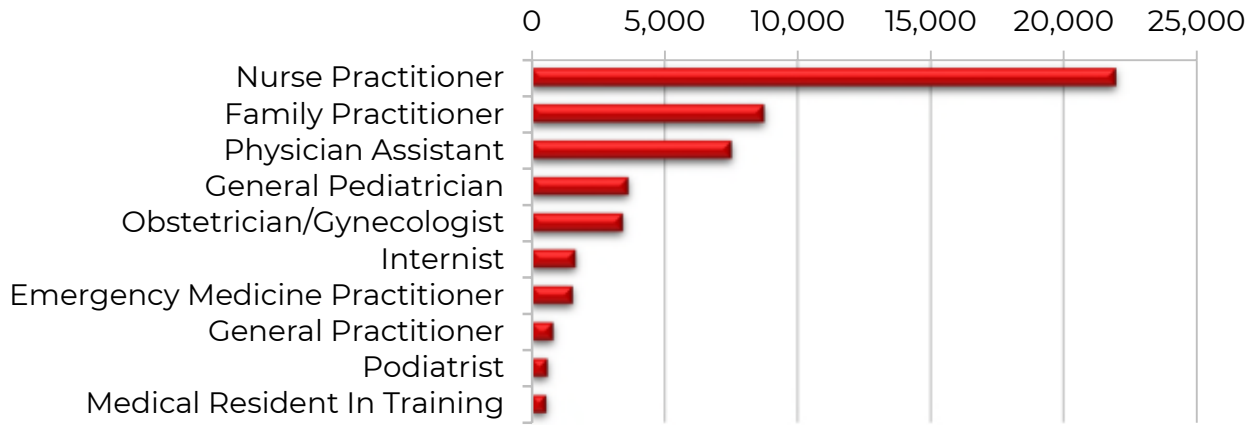
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	27,818	40,193	$2,046,514.85	$50.92	$4.63	1,861,468	441,633
2022	36,150	53,885	$2,397,764.49	$44.50	$4.05	2,108,984	592,660
% Change	**30.00%**	**34.10%**	**17.20%**	**-12.60%**	**-12.50%**	**13.30%**	**34.20%**
Change	**8,332**	**13,692**	**$351,249.64**	**-$6.42**	**-$0.58**	**247,516**	**151,027**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

Demographics of Members Utilizing Systemic Antifungal Medications



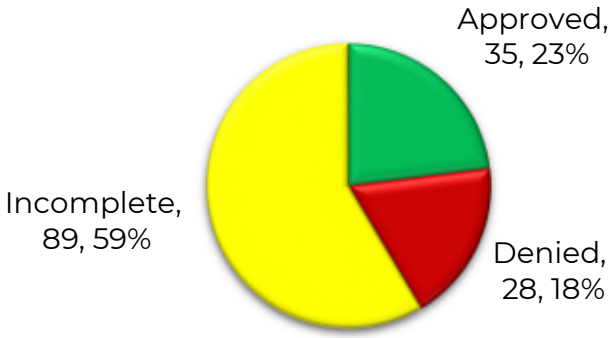
Top Prescriber Specialties of Systemic Antifungal Medications by Number of Claims



Prior Authorization of Systemic Antifungal Medications

There were 152 prior authorization requests submitted for systemic antifungal medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2,3,4]

Anticipated Patent Expiration(s):

- Cresemba® [isavuconazonium intravenous (IV) powder for solution]: October 2025
- Cresemba® (isavuconazonium capsule): September 2027
- Noxafil® (posaconazole IV solution): February 2033
- Tolsura® (itraconazole capsule): June 2033
- Vivjoa® (oteseconazole capsule): March 2036
- Brexafemme® (ibrexafungerp tablet): June 2039

New U.S. Food and Drug Administration (FDA) Approval(s):

- **April 2022:** The FDA approved Vivjoa® (oteseconazole) to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential.
- **December 2022:** The FDA approved a new indication for Brexafemme® (ibrexafungerp) tablets to reduce the incidence of RVVC in adults and post-menarchal women. The reduction in RVVC dosing regimen is 300mg (2 tablets) once and then again 12 hours later on day 1, then repeated monthly for 6 months.
- **March 2023:** The FDA approved Rezzayo™ (rezafungin) for the treatment of candidemia and invasive candidiasis for patients 18 years of age or older with limited to no other treatment options.

Vivjoa® (Oteseconazole) Product Summary[5]

Indication(s): Vivjoa® is indicated to reduce the incidence of RVVC in females with a history of RVVC who are not of reproductive potential.

How Supplied: 150mg oral capsules

Dosing and Administration:

- Vivjoa®-only dosing regimen:
  - 600mg [(4) 150mg capsules] as a single dose on day 1
  - 450mg [(3) 150mg capsules] as a single dose on day 2
  - 150mg once a week (every 7 days) for 11 weeks beginning on day 14 (weeks 2 through 12)
- Fluconazole/Vivjoa® dosing regimen:
  - Fluconazole 150mg on day 1, day 4, and day 7
  - Vivjoa® 150mg once daily on days 14 through 20 for 7 days
  - Vivjoa® 150mg once a week (every 7 days) for 11 weeks beginning on day 28 (weeks 4 through 14)
- Vivjoa® should be taken with food.

Cost Comparison: RVVC Treatments

Medication	Cost Per Unit*	Cost Per Treatment†
Brexafemme® (ibrexafungerp) 150mg tablet	$119.82	$2,875.68
Vivjoa® (oteseconazole) 150mg capsule	$156.00	$2,808.00
fluconazole 150mg tablet	$0.55	$16.50

Costs do not reflect rebated prices or net costs. Cost based on National Average Drug Acquisition Cost (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

*Unit = tablet or capsule

†Cost per treatment based on recommended dosing for RVVC: Brexafemme®: 24 tablets for 6 months; Vivjoa®: 18 capsules for 84 days; fluconazole: 30 tablets for 6 months (fluconazole dosed as 1 tablet every 72 hours for up to 14 days then weekly for 6 months)

Recommendations

The College of Pharmacy recommends the prior authorization of Vivjoa® (oteseconazole) with the following criteria (shown in red):

Vivjoa® (Oteseconazole) Approval Criteria:

1. An FDA approved indication to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC); and
2. Member must be a female who is not pregnant, lactating, or of reproductive potential; and
3. Member has a history of RVVC with at least 3 symptomatic episodes of acute vulvovaginal candidiasis (VVC) in the previous 12 months; and
4. Member has experienced a recurrence of VVC during or following 6 months of fluconazole-only maintenance treatment for RVVC or member has a contraindication to fluconazole (e.g., hypersensitivity, drug-drug interactions); and
5. Prescriber must verify member will be monitored if taking breast cancer resistance protein (BCRP) substrates (e.g., rosuvastatin, mitoxantrone, methotrexate, topotecan, imatinib, irinotecan); and
6. A quantity limit of 18 capsules per 84 days will apply.

Additionally, the College of Pharmacy recommends the addition of prior authorization criteria for Brexafemme® (ibrexafungerp) for the diagnosis of RVVC based on the new FDA approved indication (shown in red):

Brexafemme® (Ibrexafungerp) Approval Criteria [Recurrent Vulvovaginal Candidiasis (RVVC) Diagnosis]:

1. An FDA approved indication to reduce the incidence of RVVC; and
2. Member must be an adult female or post-menarchal pediatric female; and
3. Member has a history of RVVC with at least 3 symptomatic episodes of acute vulvovaginal candidiasis (VVC) in the previous 12 months; and
4. Member has experienced a recurrence of VVC during or following 6 months of fluconazole-only maintenance treatment for RVVC or member has a contraindication to fluconazole (e.g., hypersensitivity, drug-drug interactions); and
5. Prescriber must verify member is not pregnant, not lactating, and is currently using reliable contraception and will continue to use throughout the treatment duration and 4 days after last dose; and
6. Member must not be taking concurrent strong CYP3A inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin); and
7. A quantity limit of 24 tablets per 180 days will apply.

Lastly, the College of Pharmacy recommends the prior authorization of Ancobon® (flucytosine) to ensure appropriate use:

Ancobon® (Flucytosine) Approval Criteria:

1. An FDA approved indication for treatment of systemic fungal infections (e.g., sepsis, endocarditis, urinary tract infection, meningitis, pulmonary) caused by strains of *Candida* or *Cryptococcus*.

Utilization Details of Antifungal Medications: Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FLUCONAZOLE PRODUCTS						
FLUCONAZOLE TAB 150MG	29,204	20,022	$319,542.23	$10.94	1.46	13.33%
FLUCONAZOLE TAB 200MG	3,652	2,764	$51,714.99	$14.16	1.32	2.16%
FLUCONAZOLE TAB 100MG	2,667	2,147	$31,166.28	$11.69	1.24	1.30%
FLUCONAZOLE SUS 40MG/ML	1,297	1,046	$43,185.02	$33.30	1.24	1.80%
FLUCONAZOLE SUS 10MG/ML	931	815	$22,274.03	$23.92	1.14	0.93%
FLUCONAZOLE TAB 50MG	29	23	$453.92	$15.65	1.26	0.02%
FLUCONAZOLE INJ 400MG	19	7	$1,995.69	$105.04	2.71	0.08%
FLUCONAZOLE INJ 200MG	3	3	$128.41	$42.80	1	0.01%
SUBTOTAL	**37,802**	**26,827**	**$470,460.57**	**$12.45**	**1.41**	**19.63%**
NYSTATIN PRODUCTS						
NYSTATIN SUS 100,000 U/ML	8,713	7,285	$147,094.99	$16.88	1.2	6.13%
NYSTATIN TAB 500,000 U	70	36	$2,338.72	$33.41	1.94	0.10%
SUBTOTAL	**8,783**	**7,321**	**$149,433.71**	**$17.01**	**1.2**	**6.23%**
TERBINAFINE PRODUCTS						
TERBINAFINE TAB 250MG	4,424	3,002	$68.929.26	$15.58	1.47	2.87%
SUBTOTAL	**4,424**	**3,002**	**$68,929.26**	**$15.58**	**1.47**	**2.87%**
GRISEOFULVIN PRODUCTS						
GRISEOFULVIN SUS 125MG/5ML	1,058	801	$103,874.71	$91.94	1.32	4.33%
GRISEOFULVIN TAB MICRO 500MG	394	317	$106,656.75	$283.74	1.24	4.45%
GRISEOFULVIN TAB ULTR 250MG	145	111	$32,354.97	$193.50	1.31	0.20%
GRISEOFULVIN TAB ULTR 125MG	22	18	$4,778.09	$241.50	1.22	1.35%
SUBTOTAL	**1,619**	**1,247**	**$247,664.52**	**$144.04**	**1.3**	**10.33%**
ITRACONAZOLE PRODUCTS						
ITRACONAZOLE CAP 100MG	370	179	$27,260.37	$73.68	2.07	1.14%
ITRACONAZOLE SOL 10MG/ML	48	38	$30,116.01	$627.42	1.26	1.26%
SPORANOX SOL 10MG/ML	2	2	$1,734.77	$867.39	1	0.07%
SUBTOTAL	**420**	**219**	**$59,111.15**	**$140.74**	**1.92**	**2.47%**
VORICONAZOLE PRODUCTS						
VORICONAZOLE INJ 200MG	243	174	$892,377.83	$3,672.34	1.4	37.22%
VORICONAZOLE TAB 200MG	125	61	$16,500.04	$132.00	2.05	0.32%
VORICONAZOLE TAB 50MG	17	4	$7,587.84	$446.34	4.25	0.63%
VORICONAZOLE SUS 40MG/ML	12	6	$14,988.95	$1,249.08	2	0.69%
SUBTOTAL	**397**	**245**	**$931,454.66**	**$2,346.23**	**1.62**	**38.86%**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE TRO 10MG	179	159	$5,109.88	$28.55	1.13	0.21%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**179**	**159**	**$5,109.88**	**$28.55**	**1.13**	**0.21%**
POSACONAZOLE PRODUCTS						
POSACONAZOLE TAB 100MG DR	108	31	$153,278.05	$1,419.24	3.48	6.39%
NOXAFIL TAB 100MG	2	2	$13,043.52	$6,521.76	1	0.54%
SUBTOTAL	**110**	**33**	**$166,321.57**	**$1,512.01**	**3.33**	**6.93%**
ECHINOCANDIN PRODUCTS						
MICAFUNGIN INJ 100MG	86	41	$159,278.78	$1,852.08	2.1	6.64%
MICAFUNGIN INJ 50MG	5	4	$2,023.19	$404.64	1.25	0.08%
ERAXIS INJ 100MG	3	1	$3,848.03	$1,282.68	3	0.16%
MYCAMINE INJ 100MG	2	1	$5,632.82	$2,816.41	2	0.23%
SUBTOTAL	**96**	**47**	**$170,787.82**	**$1,778.99**	**2.04**	**7.11%**
ISAVUCONAZONIUM PRODUCTS						
CRESEMBA CAP 186MG	19	4	$109,930.57	$5,785.82	4.75	4.58%
SUBTOTAL	**19**	**4**	**$109,930.57**	**$5,785.82**	**4.75**	**4.58%**
AMPHOTERICIN B PRODUCTS						
AMPHOTERICIN POW	8	7	$92.83	$11.60	1.14	0.00%
AMBISOME INJ 50MG	4	1	$2,247.00	$561.75	4	0.09%
AMPHOTERICIN INJ 50MG	2	1	$102.42	$51.21	2	0.00%
SUBTOTAL	**14**	**9**	**$2,442.25**	**$174.45**	**1.56**	**0.09%**
MICONAZOLE PRODUCTS						
MICONAZOLE POWDER	10	8	$304.68	$30.47	1.25	0.01%
SUBTOTAL	**10**	**8**	**$304.68**	**$30.47**	**1.25**	**0.01%**
IBREXAFUNGERP PRODUCTS						
BREXAFEMME TAB 150MG	6	6	$2,931.96	$488.66	1	0.12%
SUBTOTAL	**6**	**6**	**$2,931.96**	**$488.66**	**1**	**0.12%**
FLUCYTOSINE PRODUCTS						
FLUCYTOSINE CAP 500MG	5	5	$12,867.65	$2,573.53	1	0.54%
SUBTOTAL	**5**	**5**	**$12,867.65**	**$2,573.53**	**1**	**0.54%**
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE TAB 200MG	1	1	$19.24	$19.24	1	0.00%
SUBTOTAL	**1**	**1**	**$19.24**	**$19.24**	**1**	**0.00%**
TOTAL	**53,885**	**36,150***	**$2,397,764.49**	**$44.50**	**1.49**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; INJ = injection; MICRO = microcrystalline; POW = powder; SOL = solution; SUS = suspension; TAB = tablet; TRO = troche; U = units; ULTR = ultramicrocrystalline

[1] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 03/2023. Last accessed 03/29/2023.
[2] Cosdon N. FDA Approves Oteseconazole, First and Only Treatment for Chronic Yeast Infection. *Contagion Live*. Available online at: https://www.contagionlive.com/view/fda-approves-oteseconazole-first-and-only-treatment-for-chronic-yeast-infection. Issued 04/28/2022. Last accessed 03/29/2023.
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Appendix O

Calendar Year 2022 Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension)

Oklahoma Health Care Authority
April 2023

Current Prior Authorization Criteria

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA†**
dexlansoprazole (Dexilant® caps)	pantoprazole (Protonix® I.V.)	esomeprazole (Nexium® I.V.)	bismuth subcitrate potassium/metronidazole/ tetracycline (Pylera® capsule)
esomeprazole (Nexium® caps)		esomeprazole strontium caps	bismuth subsalicylate/ metronidazole/tetracycline (Helidac® Therapy dose pack)
esomeprazole (Nexium® packet) – **Brand Preferred**		omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)
lansoprazole (Prevacid® caps)		pantoprazole (Protonix® susp)	esomeprazole kit (ESOMEP-EZS™)
lansoprazole ODT (Prevacid® ODT) – **Brand Preferred**		rabeprazole (Aciphex® sprinkles)	famotidine (Pepcid® susp)
omeprazole (Prilosec® caps)			glycopyrrolate (Glycate® tabs)
pantoprazole (Protonix® tabs)			glycopyrrolate ODT (Dartisla® ODT)
rabeprazole (Aciphex® tabs)			nizatidine (Axid® caps & soln)
sucralfate susp (Carafate®) – **Brand Preferred**			omeprazole/ amoxicillin/rifabutin (Talicia® caps)
			omeprazole/sodium bicarbonate (Zegerid® caps & pack)
			sucralfate susp (generic)

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reasoning for use.
†Individual criteria specific to each product applies.
caps = capsules; I.V. = intravenous; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tabs = tablet

Anti-Ulcer Medications Tier-2 Approval Criteria:

1. A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

Anti-Ulcer Medications Tier-3 Approval Criteria:

1. A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications; and
4. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and intravenous (IV) solutions require special reasoning for use.

Proton Pump Inhibitors for Pediatric Members Approval Criteria:

1. A recent 14-day trial of an H_2 receptor antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Recurrent or severe disease such as:
    a. Gastrointestinal (GI) bleed; or
    b. Zollinger-Ellison Syndrome or similar disease; and
3. Tier structure rules still apply.

Axid® (Nizatidine Capsule) Approval Criteria:

1. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.

Axid® (Nizatidine Solution) Approval Criteria:

1. A previous 14-day trial of famotidine suspension or a patient-specific, clinically significant reason why famotidine suspension is not appropriate for the member must be provided; and
2. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

Dartisla® ODT [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved indication of adjunctive treatment of peptic ulcer disease (PUD) in members 18 years of age and older; and

2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided; and
3. A quantity limit of 120 tablets per 30 days will apply.

Esomep-EZS™ (Esomeprazole Kit) Approval Criteria:

1. A previous 14-day trial of esomeprazole magnesium and a patient-specific, clinically significant reason why other lower tiered proton pump inhibitors, including omeprazole and esomeprazole, along with over-the-counter (OTC) pill swallowing spray are not appropriate for the member must be provided; and
2. Current Tier structure rules will also apply.

Glycate® (Glycopyrrolate Tablets) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of peptic ulcer disease (PUD) in members 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided.

Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/ Tetracycline Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus a histamine type 2 receptor (H_2) antagonist], must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H_2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
5. For Helidac® Therapy, a quantity limit of 224 tablets/capsules per 14 days will apply; and
6. For Pylera®, a quantity limit of 120 capsules per 10 days will apply.

Pepcid® (Famotidine Suspension) Approval Criteria:

1. Famotidine suspension will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.

Generic Sucralfate Suspension Approval Criteria:

1. Authorization consideration requires a patient-specific, clinically significant reason why the member cannot use brand name Carafate® (sucralfate) suspension.

Tagamet® (Cimetidine Tablet) Approval Criteria:

1. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy regimens approved for the same diagnosis (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
3. A quantity limit of 168 capsules per 14 days will apply.

Zegerid® (Omeprazole/Sodium Bicarbonate Capsule) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided.

Utilization of Anti-Ulcer Medications: Calendar Year 2022

Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	55,928	168,927	$5,442,166.29	$32.22	$0.77	10,462,396	7,082,085
2022	73,487	223,994	$5,977,084.77	$26.68	$0.59	13,993,999	10,101,266
% Change	**31.4%**	**32.6%**	**9.8%**	**-17.2%**	**-23.4%**	**33.8%**	**42.6%**
Change	**17,559**	**55,067**	**$534,918.48**	**-$5.54**	**-$0.18**	**3,531,603**	**3,019,181**

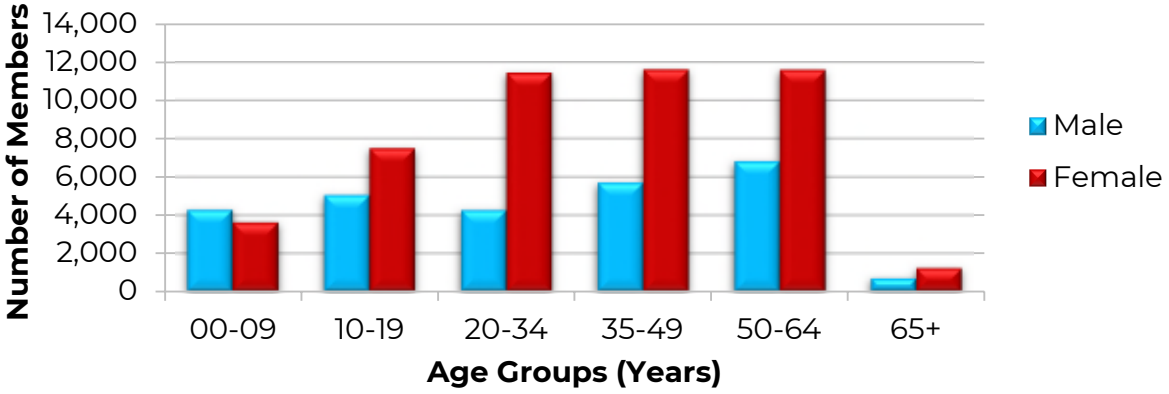
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

- Aggregate drug rebates collected during fiscal year 2022 (07/01/2021 to 06/30/2022) for anti-ulcer medications totaled $1,942,171.16.[Δ] Rebates are

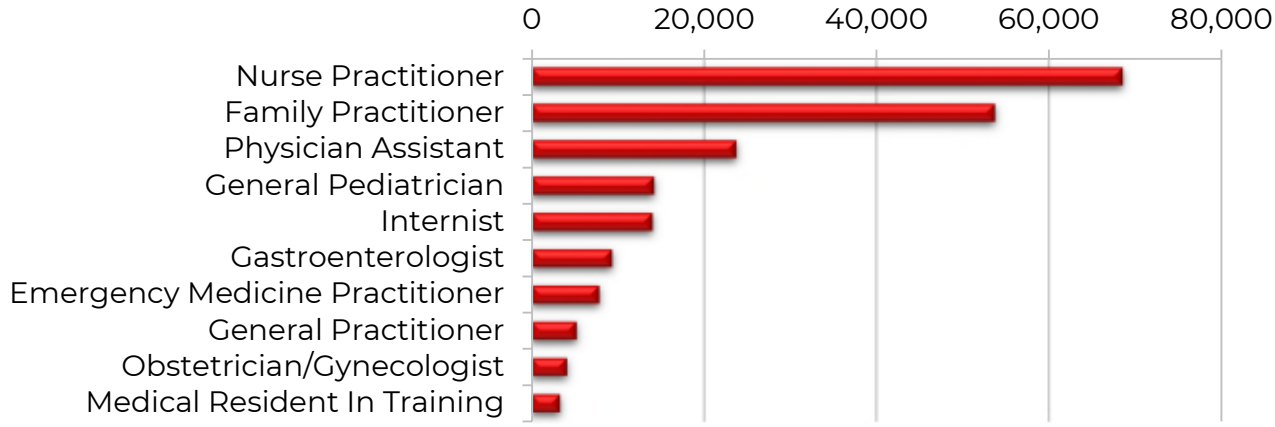
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2022 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2022 are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Anti-Ulcer Medications

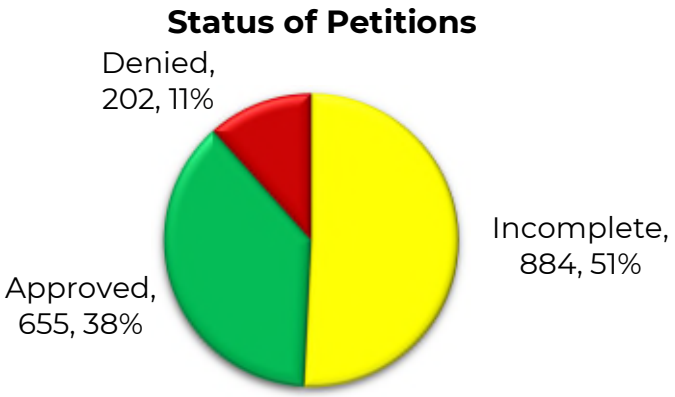


Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims



Prior Authorization of Anti-Ulcer Medications

There were 1,741 prior authorization requests submitted for anti-ulcer medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.



Market News and Updates[1,2,3,4,5,6]

Anticipated Patent Expiration(s):

- Voquezna™ Triple Pak™ (vonoprazan/amoxicillin/clarithromycin): August 2030
- Voquezna™ Dual Pak™ (vonoprazan/amoxicillin): August 2030
- Dexilant® (dexlansoprazole): March 2032
- Talicia® (omeprazole/amoxicillin/rifabutin): February 2034
- Konvomep™ (omeprazole/sodium bicarbonate for oral suspension): July 2039

U.S. Food and Drug Administration (FDA) Approval(s):

- **May 2022:** The FDA approved Voquezna™ Dual Pak™ (vonoprazan/amoxicillin) and Voquezna™ Triple Pak™ (vonoprazan/amoxicillin/clarithromycin) for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults. Voquezna™ treatment regimens contain antibiotics that are packaged with vonoprazan, a potassium-competitive acid blocker (PCAB). Phathom Pharmaceuticals has still been unable to launch the product after receiving complete response letters (CRLs) from the FDA due to testing revealing trace levels of a suspected carcinogen in the treatment. Phathom is currently working on stability testing to show that the levels of the carcinogen will not increase beyond the 96 nanograms per day level. Currently there is no federal drug rebate for Voquezna™ and thus Voquezna™ is not a covered product by SoonerCare.
- **September 2022:** The FDA approved Konvomep™ (omeprazole/sodium bicarbonate for oral suspension) for the treatment of active benign gastric ulcer and reduction of risk of upper gastrointestinal bleeding in critically ill patients, in adults. It is available as 2mg of omeprazole and 84mg of sodium bicarbonate per mL after reconstitution in 90mL, 150mL, or 300mL bottles. Konvomep™ should be reconstituted by a health care provider and is stable for up to 30 days after reconstitution. The Wholesale Acquisition Cost of Konvomep™ ranges from $1.17 per mL for

the 300mL bottle to $1.94 per mL for the 90mL bottle, resulting in a total monthly cost range of $702 to $1,164 respectively, at the recommended dose of 40mg of omeprazole once daily.

Recommendations

The College of Pharmacy recommends the following changes to the anti-ulcer medications Product Based Prior Authorization (PBPA) category (changes shown in red):

1. The prior authorization of Konvomep™ (omeprazole/sodium bicarbonate for oral suspension) and placement into the Special PA Tier with criteria similar to Zegerid® (omeprazole/sodium bicarbonate capsules); and
2. Removing the brand preferred status for sucralfate suspension (Carafate®) based on net costs; and
3. Moving Pylera® (bismuth subcitrate potassium/metronidazole/ tetracycline) from the Special PA Tier to Tier-1 based on net costs; and
4. Updating the Talicia® (omeprazole/amoxicillin/rifabutin) approval criteria to require a reason why the member cannot use Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline) based on net costs; and
5. The removal of Helidac® (bismuth subsalicylate/metronidazole/ tetracycline) due to product discontinuation.

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® capsule)	pantoprazole (Protonix® I.V.)	esomeprazole (Nexium® I.V.)	~~bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® capsule)~~
dexlansoprazole (Dexilant® caps)		esomeprazole strontium caps	~~bismuth subsalicylate/ metronidazole/ tetracycline (Helidac® Therapy dose pack)~~
esomeprazole (Nexium® caps)		omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)
esomeprazole (Nexium® packet) – **Brand Preferred**		pantoprazole (Protonix® susp)	esomeprazole kit (ESOMEP-EZS™)
lansoprazole (Prevacid® caps)		rabeprazole (Aciphex® sprinkles)	famotidine (Pepcid® susp)

lansoprazole ODT (Prevacid® ODT) – **Brand Preferred**			glycopyrrolate (Glycate® tabs)
omeprazole (Prilosec® caps)			glycopyrrolate ODT (Dartisla® ODT)
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/ amoxicillin/rifabutin (Talicia® caps)
sucralfate susp (Carafate®) – ~~**Brand Preferred**~~			omeprazole/sodium bicarbonate (Konvomep™ for oral suspension)
			omeprazole/sodium bicarbonate (Zegerid® caps & pack)
			~~sucralfate susp (generic)~~

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reasoning for use.
†Individual criteria specific to each product applies.
caps = capsules; I.V. = intravenous; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tabs = tablet

~~**Generic Sucralfate Suspension Approval Criteria:**~~

~~1. Authorization consideration requires a patient specific, clinically significant reason why the member cannot use brand name Carafate® (sucralfate) suspension.~~

~~**Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/ Tetracycline Capsule) Approval Criteria:**~~

~~1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus an histamine type 2 receptor (H_2) antagonist], must be provided; and~~
~~3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H_2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and~~

~~4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and~~
~~5. For Helidac® Therapy, a quantity limit of 224 tablets/capsules per 14 days will apply; and~~
~~6. For Pylera®, a quantity limit of 120 capsules per 10 days will apply.~~

Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension) and Zegerid® (Omeprazole/Sodium Bicarbonate Capsules) Approval Criteria:

1. Member must be 18 years of age or older; and
2. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided; and
3. For Konvomep™, requests for the 90mL or 150mL package size will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size.

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsules) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy regimens approved for the same diagnosis (e.g., omeprazole, amoxicillin, and clarithromycin) or Pylera® (bismuth subcitrate potassium/ metronidazole/tetracycline), which are available without prior authorization, must be provided; and
3. A quantity limit of 168 capsules per 14 days will apply.

Utilization Details of Anti-Ulcer Medications: Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 UTILIZATION					
OMEPRAZOLE PRODUCTS					
OMEPRAZOLE CAP 20MG	48,654	19,086	$558,074.59	$11.47	2.55
OMEPRAZOLE CAP 40MG	40,781	15,549	$531,795.90	$13.04	2.62
OMEPRAZOLE CAP 10MG	2,230	923	$31,650.94	$14.19	2.42
SUBTOTAL	**91,665**	**35,558**	**$1,121,521.43**	**$12.24**	**2.58**
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE TAB 40MG	49,661	19,096	$649,215.04	$13.07	2.6
PANTOPRAZOLE TAB 20MG	7,544	3,286	$96,419.99	$12.78	2.3
SUBTOTAL	**57,205**	**22,382**	**$745,635.03**	**$13.03**	**2.56**
FAMOTIDINE PRODUCTS					
FAMOTIDINE TAB 20MG	22,419	11,315	$276,438.78	$12.33	1.98
FAMOTIDINE TAB 40MG	6,785	3,308	$92,917.75	$13.69	2.05
FAMOTIDINE INJ 10MG/ML	249	14	$4,052.90	$16.28	17.79

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FAMOTIDINE INJ 200MG/20ML	162	14	$3,261.87	$20.14	11.57
FAMOTIDINE INJ 20MG/2ML	45	8	$796.82	$17.71	5.63
FAMOTIDINE INJ 40MG/4ML	25	4	$670.43	$26.82	6.25
SUBTOTAL	**29,685**	**14,663**	**$378,138.55**	**$12.74**	**2.02**
SUCRALFATE PRODUCTS					
SUCRALFATE TAB 1GM	10,450	6,270	$246,035.18	$23.54	1.67
CARAFATE SUS 1GM/10ML	816	466	$306,439.81	$375.54	1.75
SUBTOTAL	**11,266**	**6,736**	**$552,474.99**	**$49.04**	**1.67**
ESOMEPRAZOLE PRODUCTS					
ESOMEPRAZOLE CAP 40MG DR	4,821	1,673	$95,794.90	$19.87	2.88
ESOMEPRAZOLE CAP 20MG DR	1,912	779	$40,577.67	$21.22	2.45
NEXIUM GRA 10MG DR	689	223	$207,332.25	$300.92	3.09
NEXIUM GRA 20MG DR	458	101	$138,082.95	$301.49	4.53
NEXIUM GRA 5MG DR	315	134	$90,116.18	$286.08	2.35
NEXIUM GRA 2.5MG DR	192	84	$54,615.29	$284.45	2.29
NEXIUM GRA 40MG DR	166	38	$46,844.26	$282.19	4.37
NEXIUM CAP 40MG	3	1	$2,401.39	$800.46	3
SUBTOTAL	**8,556**	**3,033**	**$675,764.89**	**$78.98**	**2.82**
DEXLANSOPRAZOLE PRODUCTS					
DEXLANSOPRAZOLE CAP 60MG DR	2,581	555	$618,349.73	$239.58	4.65
DEXILANT CAP 60MG DR	1,681	473	$492,097.99	$292.74	3.55
DEXLANSOPRAZOLE CAP 30MG DR	605	140	$150,395.62	$248.59	4.32
DEXILANT CAP 30MG DR	428	114	$128,340.76	$299.86	3.75
SUBTOTAL	**5,295**	**1282**	**$1,389,184.10**	**$262.36**	**4.13**
LANSOPRAZOLE PRODUCTS					
LANSOPRAZOLE CAP 30MG DR	2,369	765	$35,151.26	$14.84	3.1
LANSOPRAZOLE CAP 15MG DR	497	201	$9,916.21	$19.95	2.47
LANSOPRAZOLE TAB 15MG ODT	351	100	$55,942.72	$159.38	3.51
LANSOPRAZOLE TAB 30MG ODT	308	61	$49,115.56	$159.47	5.05
PREVACID TAB 15MG STB	57	14	$26,099.19	$457.88	4.07
LANSOPRAZOLE TAB 30MG	48	15	$7,553.70	$157.37	3.2
PREVACID TAB 30MG STB	46	8	$21,106.26	$458.83	5.75
SUBTOTAL	**3,676**	**1164**	**$204,884.90**	**$55.74**	**3.16**
GLYCOPYRROLATE PRODUCTS					
GLYCOPYRROLATE TAB 1MG	1,581	348	$28,856.57	$18.25	4.54
GLYCOPYRROLATE TAB 2MG	973	148	$22,073.51	$22.69	6.57
SUBTOTAL	**2,554**	**496**	**$50,930.08**	**$19.94**	**5.15**
RABEPRAZOLE PRODUCTS					
RABEPRAZOLE TAB 20MG	547	199	$11,985.37	$21.91	2.75
SUBTOTAL	**547**	**199**	**$11,985.37**	**$21.91**	**2.75**
CIMETIDINE PRODUCTS					
CIMETIDINE SOL 300MG/5ML	176	121	$8,055.85	$45.77	1.45
SUBTOTAL	**176**	**121**	**$8,055.85**	**$45.77**	**1.45**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 SUBTOTAL	**210,625**	**85,634**	**$5,138,575.19**	**$24.20**	**2.46**
TIER-2 UTILIZATION					
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE INJ SOD 40MG	82	3	$3,188.68	$38.89	27.33
PROTONIX INJ 40MG	9	1	$422.46	$46.94	9
SUBTOTAL	**91**	**4**	**$3,611.14**	**$39.68**	**22.75**
TIER-2 SUBTOTAL	**91**	**4**	**$3,611.14**	**$39.68**	**22.75**
TIER-3 UTILIZATION					
PANTOPRAZOLE PRODUCTS					
PROTONIX PAK 40MG	13	2	$6,304.35	$484.95	6.5
SUBTOTAL	**13**	**2**	**$6,304.35**	**$484.95**	**6.5**
OMEPRAZOLE PRODUCTS					
PRILOSEC POW 10MG	2	1	$813.98	$406.99	2
PRILOSEC POW 2.5MG	1	1	$410.12	$410.12	1
SUBTOTAL	**3**	**2**	**$1,224.10**	**$408.03**	**1.50**
TIER-3 SUBTOTAL	**16**	**4**	**$7,528.45**	**$470.53**	**4**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
FAMOTIDINE PRODUCTS					
FAMOTIDINE SUS 40MG/5ML	12,686	5,326	$713,043.31	$56.21	2.38
SUBTOTAL	**12,686**	**5,326**	**$713,043.31**	**$56.21**	**2.38**
SUCRALFATE PRODUCTS					
SUCRALFATE SUS 1GM/10ML	429	316	$91,275.38	$212.76	1.36
SUBTOTAL	**429**	**316**	**$91,275.38**	**$212.76**	**1.36**
NIZATIDINE PRODUCTS					
NIZATIDINE SOL 15MG/ML	89	56	$13,865.55	$155.79	1.59
NIZATIDINE CAP 150MG	1	1	$39.34	$39.34	1
SUBTOTAL	**90**	**57**	**$13,904.89**	**$154.50**	**1.58**
CIMETIDINE PRODUCTS					
CIMETIDINE TAB 400MG	22	17	$814.04	$37.00	1.29
CIMETIDINE TAB 300MG	20	8	$608.29	$30.41	2.5
CIMETIDINE TAB 200MG	4	2	$91.88	$22.97	2
CIMETIDINE TAB 800MG	3	3	$177.83	$59.28	1
SUBTOTAL	**49**	**30**	**$1,692.04**	**$34.53**	**1.63**
TRIPLE THERAPY COMBINATIONS					
TALICIA CAP 10/250/12.5MG	7	7	$4,822.06	$688.87	1
SUBTOTAL	**7**	**7**	**$4,822.06**	**$688.87**	**1**
OMEPRAZOLE/SODIUM BICARBONATE PRODUCTS					
OMEPRAZOLE/BICARB POW 20/1,680MG	1	1	$2,632.31	$2,632.31	1
SUBTOTAL	**1**	**1**	**$2,632.31**	**$2,632.31**	**1**
SPECIAL PA SUBTOTAL	**13,262**	**5,737**	**$827,369.99**	**$62.39**	**2.31**
TOTAL	**223,994**	**73,487***	**$5,977,084.77**	**$26.68**	**3.05**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BICARB = bicarbonate; CAP = capsule; DR = delayed-release; GRA = granules; INJ = injection; ODT = orally disintegrating tablet; PAK = pack; POW = powder; SOD = sodium; SOL = solution; SPR = sprinkle; STB = SoluTab; SUS = suspension; TAB = tablet

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 03/2023. Last accessed 03/08/2023.

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[6] Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension) Prescribing Information. Azurity Pharmaceuticals, Inc. Available online at: https://konvomep.com/wp-content/uploads/2023/02/Konvomep-PI-LongVersionforWebsite-Dec2022-REV01.pdf. Last revised 12/2022. Last accessed 03/15/2023.

Appendix P

30-Day Notice to Prior Authorize Filspari™ (Sparsentan)

Oklahoma Health Care Authority
April 2023

Introduction[1,2,3,4]

Immunoglobulin A nephropathy (IgAN), also known as Berger's Disease, is an autoimmune kidney disease that impairs the kidney's ability to filter, leading to kidney failure in approximately 25%-35% of patients within 20-25 years of presentation. IgAN is estimated to be the most common cause of primary glomerulonephritis, however the disease may go undetected for many years because in the earlier stages, most patients are asymptomatic and the disease may resolve entirely on its own in some patients. In patients with IgAN, the body creates abnormal IgA proteins, which accumulate in the kidney, causing inflammation and damage to the glomeruli. The most common symptom of IgAN is hematuria especially after a respiratory infection as IgA levels are increased in the body. Other symptoms of IgAN include flank pain, swelling in the ankles, and high blood pressure. Although IgAN can be suspected in a patient based on symptoms and physical exam, the only definitive way to diagnosis IgAN is through a kidney biopsy.

There is currently no cure for IgAN. The management of IgAN focuses on optimized supportive care to slow the progression of the disease. The Kidney Disease: Improving Global Outcomes (KDIGO) 2021 practice guidelines, recommend blood pressure control to optimal targets, reduction of proteinuria with renin-angiotensin system (RAS) inhibition, and lifestyle modifications, including weight reduction, exercise, smoking cessation, and dietary sodium restriction. Angiotensin converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARB) are recommended for patients with proteinuria >0.5g per day, regardless of blood pressure control. Elevated proteinuria is a risk factor for disease progression in patients with IgAN; therefore, remission of proteinuria is a surrogate marker for efficacy of treatment in patients with IgAN. Based on the APPROACH study, about 50% of patients with IgAN reached disease remission with use of an ACE inhibitor or an ARB. According to the KDIGO guidelines, patients at high risk of rapid disease progression are defined as having persistent proteinuria >0.75g-1g/day despite 3 months of optimized supportive care. At that point, the guidelines recommend the use of corticosteroids, despite their toxicity, for a maximum of 6 months.

In February 2023, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Filspari™ (sparsentan) to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine

protein-to-creatinine ratio (UPCR) ≥1.5g/g. The approval of Filspari™, granted under the FDA's accelerated approval pathway, is based on improvements in proteinuria compared to an active comparator (irbesartan) in the ongoing Phase 3 PROTECT study.

Filspari™ (Sparsentan) Product Summary[5]

Indication(s): Filspari™ is indicated to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5 g/g.

- This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Filspari™ slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

How Supplied: 200mg and 400mg oral tablets

Dosing and Administration:

- Prior to initiating treatment with Filspari™, use of renin-angiotensin-aldosterone system (RAAS) inhibitors or endothelin receptor antagonists (ERAs) should be discontinued.
- Filspari™ should be initiated at 200mg orally once daily. After 14 days, the dose should be increased to the recommended dose of 400mg once daily, as tolerated.
- Tablets should be swallowed whole with water prior to the morning or evening meal.

Cost: The Wholesale Acquisition Cost (WAC) of Filspari™ is $330 per tablet for either the 200mg or 400mg tablet, resulting in an estimated cost of $9,900 per 30 days and $118,800 per year based on the recommended once daily dose.

Recommendations

The College of Pharmacy recommends the prior authorization of Filspari™ (sparsentan) with the following criteria (shown in red):

Filspari™ (Sparsentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy; and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and

3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite 3 months of maximal supportive care:
   a. Urine protein-to-creatinine (UPCR) ratio ≥1.5g/g; or
   b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
7. Prescriber must verify the member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) prior to initiating treatment with Filspari™; and
8. Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari™; and
9. Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs); and
10. If member is using antacids, they must agree to separate antacid and Filspari™ administration by 2 hours; and
11. Prescriber, pharmacy, and member must be enrolled in the Filspari™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. A quantity limit of 30 tablets per 30 days will apply.

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[1] National Organization for Rare Disorders (NORD). IgA Nephropathy. Available online at: https://rarediseases.org/rare-diseases/iga-nephropathy/. Last revised 01/2022. Last accessed 03/22/2023.
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[3] Bagchi S, Mani K, Swamy A, et al. Supportive Management of IgA Nephropathy with Renin-Angiotensin Blockage, the AIIMS Primary IgA Nephropathy Cohort (APPROACH) Study. *Kidney International* 2021; 6(6):1661-1668. doi.org/10.1016/j.ekir.2021.02.018.
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[5] Filspari™ (Sparsentan) Prescribing Information. Travere Therapeutics, Inc. Available online at: https://filspari.com/igan/filspari-prescribing-information.pdf. Last revised 02/2023. Last accessed 03/08/2023.

Appendix Q

Calendar Year 2022 Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Doral® (Quazepam)

Oklahoma Health Care Authority
April 2023

Current Prior Authorization Criteria

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	daridorexant (Quviviq™)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)
flurazepam (Dalmane®)			tasimelteon (Hetlioz®, Hetlioz LQ)†
ramelteon (Rozerem®) – **Brand Preferred**			temazepam (Restoril®) 7.5mg and 22.5mg
temazepam (Restoril®) 15mg and 30mg			zolpidem SL tablets (Edluar®)
triazolam (Halcion®)			zolpidem SL tablets (Intermezzo®)
zaleplon (Sonata®)			zolpidem oral spray (Zolpimist®)
zolpidem (Ambien®)			

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.
†Individual criteria specific to tasimelteon applies.
CR = controlled release; PA = prior authorization; SL = sublingual

- Tier-1 medications are available without a prior authorization for members 19 years of age and older.
- Members 18 years of age or younger will be required to submit a prior authorization for consideration of all insomnia medications.
- All medications have a quantity limit of 30 units per 30 days.

Insomnia Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and

3. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
4. Approvals will be granted for the duration of 6 months.

Insomnia Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. Member must have a minimum of a 30-day trial with at least 2 Tier-2 medications; and
    a. If only 1 Tier-2 medication is available, a minimum of a 30-day trial with 1 Tier-2 medication will be required; and
4. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
5. Approvals will be granted for the duration of 6 months.

Hetlioz® (Tasimelteon Capsule) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Non-24-Hour Sleep-Wake Disorder (Non-24) confirmed by a sleep specialist; or
    b. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 18 years of age or older for a diagnosis of Non-24 or 16 years of age or older for a diagnosis of SMS; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
5. A quantity limit of 30 capsules for 30 days will apply.

Hetlioz LQ™ (Tasimelteon Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 3 to 15 years of age; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the Hetlioz LQ™ package labeling; and
5. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.

Ramelteon (Generic Rozerem®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand formulation (Rozerem®) of ramelteon must be provided.

Seconal Sodium™ (Secobarbital Sodium Capsule) Approval Criteria:

1. An FDA approved indication for 1 of the following:
   a. The short-term treatment of insomnia; or
   b. A preanesthetic; and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives must be provided; and
3. For the short-term treatment of insomnia, a quantity limit of 1 capsule per day not to exceed 14 capsules per 30 days will apply.

Utilization of Insomnia Medications: Calendar Year 2022

Comparison of Calendar Years

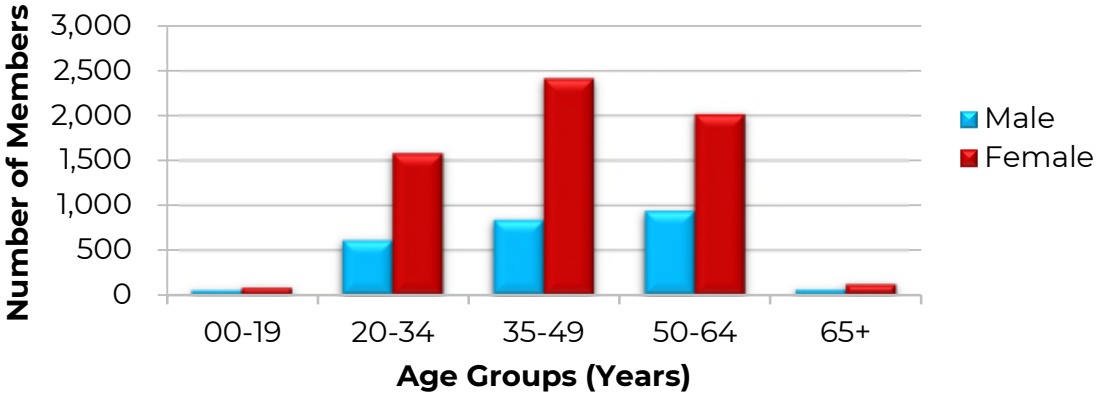
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	5,781	24,989	$1,127,456.69	$45.12	$1.60	706,325	706,461
2022	8,665	35,468	$1,544,423.68	$43.54	$1.58	974,483	975,745
% Change	**49.9%**	**41.9%**	**37.0%**	**-3.5%**	**-1.3%**	**38.0%**	**38.1%**
Change	**2,884**	**10,479**	**$416,966.99**	**-$1.58**	**-$0.02**	**268,158**	**269,284**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

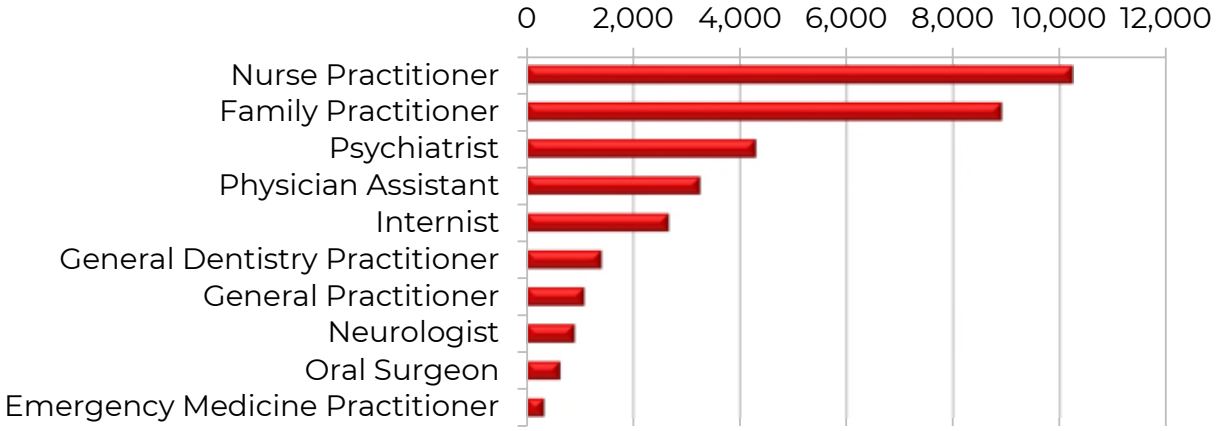
- Aggregate drug rebates collected during fiscal year 2022 (07/01/2021 to 06/30/2022) for insomnia medications totaled $930,690.53.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2022 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2022 are still being collected at this time. The costs included in this report do not reflect net costs.

[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Demographics of Members Utilizing Insomnia Medications



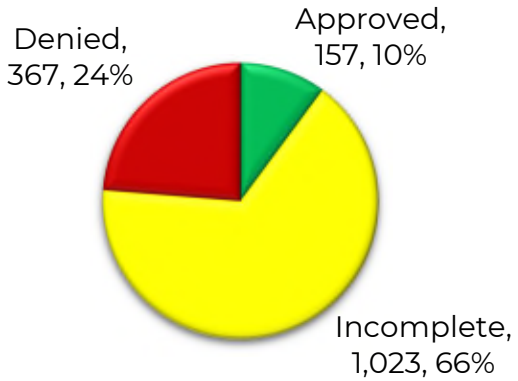
Top Prescriber Specialties of Insomnia Medications by Number of Claims



Prior Authorization of Insomnia Medications

There were 1,547 prior authorization requests submitted for insomnia medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Doral® (quazepam tablets): June 2028
- Silenor® (doxepin tablets): September 2030
- Edluar® (zolpidem sublingual tablets): February 2031
- Zolpimist® (zolpidem oral spray): August 2032
- Belsomra® (suvorexant tablets): May 2033
- Quviviq™ (daridorexant tablets): December 2034
- Hetlioz® (tasimelteon capsules): August 2035
- Dayvigo® (lemborexant tablets): October 2035
- Hetlioz LQ™ (tasimelteon oral suspension): December 2040

News:

- **April 2023:** Galt Pharmaceuticals, the current manufacturer of Doral® (quazepam), began participating in the federal Medicaid prescription drug rebate program (MDRP) in April 2023. Doral® was approved by the FDA in 1985 for the treatment of insomnia.

Doral® (Quazepam) Product Summary[2]

Indication(s): Doral® is a benzodiazepine indicated for the treatment of insomnia in adults.

How Supplied: 15mg functionally scored oral tablet

Dosing:

- The recommended initial dose is 7.5mg. The 15mg tablet should be split along the score line to achieve 7.5mg dose.
- The dose may be increased to a maximum of 15mg if necessary for efficacy. The lowest effective dose should be used.

Cost: The Wholesale Acquisition Cost (WAC) of Doral® 15mg is $28.33 per tablet, resulting in a monthly cost of $849.90 at the maximum recommended dosage of 15mg per day.

Recommendations

The College of Pharmacy recommends the prior authorization of Doral® (quazepam) and placement into the Special Prior Authorization (PA) tier of the Insomnia Medications Product Based Prior Authorization (PBPA) category based on net cost (changes noted in red in the following PBPA Tier chart and approval criteria):

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	daridorexant (Quviviq™)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)
flurazepam (Dalmane®)			quazepam (Doral®)
ramelteon (Rozerem®) – **Brand Preferred**			tasimelteon (Hetlioz®, Hetlioz LQ™)+
temazepam (Restoril®) 15mg and 30mg			temazepam (Restoril®) 7.5mg and 22.5mg
triazolam (Halcion®)			zolpidem SL tablets (Edluar®)
zaleplon (Sonata®)			zolpidem SL tablets (Intermezzo®)
zolpidem (Ambien®)			zolpidem oral spray (Zolpimist®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.
+Individual criteria specific to tasimelteon applies.
CR = controlled release; PA = prior authorization; SL = sublingual

Utilization Details of Insomnia Medications: Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ZOLPIDEM TAB 10MG	15,821	2,919	$160,904.46	$10.17	5.42	10.42%
ZOLPIDEM TAB 5MG	3,971	1,394	$39,798.11	$10.02	2.85	2.58%
ESZOPICLONE TAB 3MG	2,922	716	$38,446.88	$13.16	4.08	2.49%
TEMAZEPAM CAP 30MG	2,752	581	$32,916.12	$11.96	4.74	2.13%
TRIAZOLAM TAB 0.25MG	2,210	1,926	$30,114.67	$13.63	1.15	1.95%
TEMAZEPAM CAP 15MG	1,689	572	$17,329.09	$10.26	2.95	1.12%
ROZEREM TAB 8MG	1,469	337	$522,466.79	$355.66	4.36	33.83%
ESZOPICLONE TAB 2MG	1,396	498	$18,514.89	$13.26	2.8	1.20%
ESZOPICLONE TAB 1MG	659	323	$9,343.89	$14.18	2.04	0.61%
ZALEPLON CAP 10MG	521	199	$7,058.64	$13.55	2.62	0.46%
ZALEPLON CAP 5MG	179	138	$1,883.68	$10.52	1.3	0.12%
TRIAZOLAM TAB 0.125MG	109	101	$1,364.17	$12.52	1.08	0.09%
ESTAZOLAM TAB 2MG	34	6	$1,507.20	$44.33	5.67	0.10%
ESTAZOLAM TAB 1MG	7	3	$219.64	$31.38	2.33	0.01%
FLURAZEPAM CAP 15MG	6	1	$129.54	$21.59	2	0.01%
FLURAZEPAM CAP 30MG	2	1	$52.04	$26.02	2	0.00%
TIER-1 SUBTOTAL	**33,747**	**9,715**	**$882,049.81**	**$26.14**	**3.47**	**57.11%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 PRODUCTS						
ZOLPIDEM ER TAB 12.5MG	1,183	195	$16,620.27	$14.05	6.07	1.08%
ZOLPIDEM ER TAB 6.25MG	129	38	$1,659.68	$12.87	3.39	0.11%
AMBIEN CR TAB 12.5MG	12	1	$6,903.73	$575.31	12	0.45%
TIER-2 SUBTOTAL	**1,324**	**39**	**$25,183.68**	**$19.02**	**33.95**	**1.63%**
TIER-3 PRODUCTS						
DAYVIGO TAB 10MG	139	12	$39,541.64	$284.47	11.58	2.56%
BELSOMRA TAB 20MG	101	23	$38,526.89	$381.45	4.39	2.49%
DAYVIGO TAB 5MG	42	16	$12,251.45	$291.70	2.63	0.79%
BELSOMRA TAB 10MG	35	11	$13,774.92	$393.57	3.18	0.89%
BELSOMRA TAB 15MG	11	1	$4,369.20	$397.20	11	0.28%
BELSOMRA TAB 5MG	1	1	395.22	$395.22	1	0.03%
TIER-3 SUBTOTAL	**329**	**64**	**$108,859.32**	**$330.88**	**5.14**	**7.05%**
SPECIAL PRIOR AUTHORIZATION (PA) PRODUCTS						
TEMAZEPAM CAP 7.5MG	24	8	$1,134.22	$47.26	3	0.07%
HETLIOZ CAP 20MG	23	2	$523,535.61	$22,762.42	11.5	33.9%
DOXEPIN TAB 6MG	7	2	$1,756.58	$250.94	3.5	0.11%
RAMELTEON TAB 8MG	5	5	$208.27	$41.65	1	0.01%
TEMAZEPAM CAP 22.5MG	5	2	$256.82	$51.36	2.5	0.02%
DOXEPIN TAB 3MG	2	2	$529.30	$264.65	1	0.03%
DARIDOREXANT 50MG	2	2	$910.07	$455.04	1	0.06%
SPECIAL PA SUBTOTAL	**68**	**23**	**$528,330.87**	**$7,769.57**	**2.96**	**34.21%**
TOTAL	**35,468**	**8,665***	**$1,544,423.68**	**$43.54**	**4.09**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CR = controlled-release; ER = extended-release; TAB = tablet

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2023. Last accessed 03/28/2023.
[2] Doral® (Quazepam) Prescribing Information. Galt Pharmaceuticals. Available online at: https://doralrx.com/docs/Doral_PI.pdf. Last revised 01/2023. Last accessed 03/19/2023.

Appendix R

Calendar Year 2022 Annual Review of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt)

Oklahoma Health Care Authority
April 2023

Current Prior Authorization Criteria

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Infantile-Onset Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of infantile-onset Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Lumizyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Late-Onset (Non-Infantile) Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Provider must document presence of symptoms of Pompe disease; and
4. Lumizyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent authorizations will be for the duration of 1 year.

Nexviazyme® (Avalglucosidase Alfa-ngpt) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and

2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Nexviazyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent authorizations will be for the duration of 1 year.

Utilization of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt): Calendar Year 2022

Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	1	46	$524,657.55	$11,405.60	46
2022	1	33	$461,394.65	$13,981.66	33
% Change	**0.00%**	**-28.26%**	**-12.06%**	**22.59%**	**-28.26%**
Change	**0%**	**-13**	**-$63,262.90**	**$2,576.06**	**-13**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

Prior Authorization of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt)

There were 3 prior authorization requests submitted for Lumizyme® (alglucosidase alfa) for 1 unique member during calendar year 2022.

Status of Petitions

Recommendations

The College of Pharmacy does not recommend any changes to the current Lumizyme® (alglucosidase alfa) and Nexviazyme® (avalglucosidase alfa-ngpt) prior authorization criteria at this time.

Utilization Details of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt): Calendar Year 2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALGLUCOSIDASE ALFA (J0221)	33	1	$461,394.65	$13,981.66	33	100%
TOTAL	**33**	**1**	**$461,394.65**	**$13,981.66**	**33**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.

Appendix S

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates*

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: April 3, 2023

FDA Moves Forward with Mail-back Envelopes for Opioid Analgesics Dispensed in Outpatient Settings

The FDA announced it is requiring manufacturers of opioid analgesics dispensed in outpatient settings to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers as an additional opioid analgesic disposal option for patients.

The FDA issued notice to all manufacturers of opioid analgesics used in outpatient settings that they are required to submit the proposed modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) within 180 days of the date of the notification letter. The FDA anticipates approval of the modified REMS in 2024. When implemented, outpatient pharmacies and other dispensers will have the option to order prepaid mail-back envelopes from opioid analgesic manufacturers, which they may then provide to patients prescribed opioid analgesics. The REMS modification also requires manufacturers to develop educational materials for patients on safe disposal of opioid analgesics, which outpatient pharmacies and other dispensers may also provide to patients.

This action follows a Federal Register notice issued in April 2022 that sought public comment on a potential modification of the OA REMS to require that mail-back envelopes be dispensed and education on safe disposal be provided with opioid analgesics dispensed in an outpatient setting.

Patients commonly report having unused opioid analgesics following surgical procedures, and many Americans gain access to opioids through friends or relatives who have unused opioids. Data shows that educating patients about disposal options may increase the disposal rate of unused opioids and that providing a disposal option along with education could further increase that rate.

Currently, there are multiple mail-back envelope programs operating in the United States and mail-back envelopes are commercially available from multiple entities. There are long-standing regulations and policies, under the DEA and United States Postal Service, in place to ensure that mail-back envelopes are nondescript, fit for purpose, and can safely and securely transport unused medicines from the patient's home to the location where they will be destroyed.

The FDA continues to consider additional ways to increase safe disposal of unused opioid analgesics. Specifically, the FDA is exploring whether manufacturers of opioid analgesic should also be required to make in-home disposal products available to patients who are prescribed opioid analgesics. In an effort to further evaluate this potential option, the FDA will participate in the workshop, Defining and Evaluating In-Home Drug Disposal Systems for Opioid Analgesics, to examine current in-home disposal options hosted by the National Academies of Sciences, Engineering and Medicine's (NASEM's) Forum on Drug Discovery, Development, and Translation in June 2023. The

FDA has also issued a Federal Register notice to seek information and comments from the public to aid their assessment of in-home disposal methods.

These collective efforts are part of the FDA's implementation of the FDA Overdose Prevention Framework that aims to prevent drug overdoses and reduce deaths through impactful and creative actions. The FDA remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose, and death in the United States through the 4 priorities of the framework, including: supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.

FDA NEWS RELEASE

For Immediate Release: March 29, 2023

FDA Approves First Over-the-Counter Naloxone Nasal Spray

The FDA approved Narcan 4mg naloxone hydrochloride nasal spray for over-the-counter (OTC), nonprescription, use – the first naloxone product approved for use without a prescription. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. Today's action paves the way for the life-saving medication to reverse an opioid overdose to be sold directly to consumers in places like drug stores, convenience stores, grocery stores, and gas stations, as well as online.

The timeline for availability and price of this OTC product is determined by the manufacturer. The FDA will work with all stakeholders to help facilitate the continued availability of naloxone nasal spray products during the time needed to implement the Narcan switch from prescription to OTC status, which may take months. Other formulations and dosages of naloxone will remain available by prescription only.

Drug overdose persists as a major public health issue in the United States, with more than 101,750 reported fatal overdoses occurring in the 12-month period ending in October 2022, primarily driven by synthetic opioids like illicit fentanyl.

Narcan nasal spray was first approved by the FDA in 2015 as a prescription drug. In accordance with a process to change the status of a drug from prescription to nonprescription, the manufacturer provided data demonstrating that the drug is safe and effective for use as directed in its proposed labeling. The manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a health care professional. The application to approve Narcan nasal spray for OTC use was granted priority review status and was the subject of an advisory committee meeting in February 2023, where committee members voted unanimously to recommend it be approved for marketing without a prescription.

The approval of OTC Narcan nasal spray will require a change in the labeling for the currently approved 4mg generic naloxone nasal spray products that rely on Narcan as their reference listed drug product. Manufacturers of these products will be required to submit a supplement to their applications to effectively switch their products to OTC status. The approval may also affect the status of other brand-name naloxone nasal spray products of 4mg or less, but determinations will be made on a case-by-case basis and the FDA may contact other firms as needed.

The use of Narcan nasal spray in individuals who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, tachycardia, fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

The FDA has taken a series of measures to help facilitate access to naloxone products. In November 2022, the FDA announced its preliminary assessment that certain naloxone products, such as the 1 ultimately approved today, have the potential to be safe and effective for OTC use and encouraged sponsors to submit applications for approval of OTC naloxone products. The FDA previously announced in 2019 that it had designed, tested, and validated a model naloxone Drug Facts Label (DFL) with easy-to-understand pictograms on how to use the drug to encourage manufacturers to pursue approval of OTC naloxone products. The model DFL was used to support the approved application along with the results of a simulated use Human Factors validation study designed to assess whether all the components of the product with which a user would interact could be used safely and effectively as intended.

Through the FDA Overdose Prevention Framework, the FDA remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose, and death in the United States. The FDA granted the OTC approval of Narcan to Emergent BioSolutions.

FDA NEWS RELEASE

For Immediate Release: March 14, 2023

FDA Authorizes Bivalent Pfizer-BioNTech COVID-19 Vaccine as Booster Dose for Certain Children 6 Months through 4 Years of Age

The FDA amended the emergency use authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide for a single booster dose of the vaccine in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with 3 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine.

For the authorization of a single booster dose of the Pfizer COVID-19 Vaccine, Bivalent for children 6 months through 4 years of age at least 2 months after completion of primary vaccination with 3 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine, the FDA evaluated immune response data from 60 children in this age group who had completed primary vaccination with 3 doses of monovalent Pfizer-BioNTech COVID-19 Vaccine and received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent in a clinical study. One month after receiving the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, the study participants demonstrated an immune response to both the original SARS-CoV-2 virus strain and to omicron BA.4/BA.5.

In addition, the authorization is supported by the FDA's previous analyses of the effectiveness of primary vaccination with the monovalent Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older and individuals 6 months through 4 years of age, and previous analyses of immune response data in adults older than 55 years of age who had received 1 booster dose with an investigational Pfizer-BioNTech bivalent COVID-19 vaccine (original and omicron BA.1).

The safety of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent as a booster dose in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with 3 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine is based on safety data previously evaluated by the FDA.

In addition, among individuals 6 months of age and older, safety was assessed in participants in 2 clinical studies. In 1 study participants 6 months through 11 years of age who were previously vaccinated with a 3-dose primary series of monovalent Pfizer-BioNTech COVID-19 Vaccine received a booster dose of the Pfizer-BioNTech COVID 19 Vaccine, Bivalent. Among 24 participants 6 months through 23 months of age, the most common side effects included irritability, drowsiness, injection site redness, pain and swelling, decreased appetite, fatigue, and fever. Among 36 participants 2 years through 4 years of age, the most common side effects included fatigue, injection site pain, redness and swelling, diarrhea, vomiting, headache, joint pain, and chills. Among 113 participants 5 through 11 years of age, the most common side effects included fatigue, headache, muscle pain, joint pain, chills, fever, vomiting, diarrhea, injection site pain, swelling and redness, and swelling of the lymph nodes in the same arm of the injection. In another study, 316 participants 12 years of age and older who were previously vaccinated with a 2-dose primary series and a single booster dose of monovalent Pfizer-BioNTech COVID-19 Vaccine, received a second booster dose with the Pfizer BioNTech COVID-19 Vaccine, Bivalent. The most commonly reported side effects by the participants in this age group were the same as those reported by the participants in the 5 through 11 years age group.

The safety data accrued with the investigational bivalent vaccine (original and omicron BA.1) and with the monovalent Pfizer-BioNTech COVID-19 Vaccine are relevant to the Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process. The amendment to the EUA was issued to Pfizer Inc.

Current Drug Shortages Index (as of March 28, 2023):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Inhalational Solution	***Currently in Shortage***
Alprostadil (Muse) Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amoxicillin Oral Powder for Suspension	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Belladonna and Opium Suppositories	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***

Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Disodium Versenate Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Capecitabine Tablets	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Chlorothiazide Oral Suspension	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablets	***Currently in Shortage***
Collagenase Ointment	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Conjugated Estrogens/Bazedoxifene (Duavee) Tablet, Film Coated	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 10% Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 5% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Diazepam Rectal Gel	***Currently in Shortage***
Diflunisal Tablets	***Currently in Shortage***
Difluprednate Ophthalmic Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol (Bal in Oil) Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dulagutide (Trulicity) Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Edetate Calcium Disodium Injection	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1mg/mL	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***

Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Iomeprol injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
IV Fat Emulsion	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablets	***Currently in Shortage***
Methotrexate Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Neomycin Sulfate Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Oxytocin Injection	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara) Injection	***Currently in Shortage***

Pentostatin Injection	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Concentrate Injection	***Currently in Shortage***
Quinapril Hydrochlorothiazide Tablets	***Currently in Shortage***
Quinapril Hydrochloride Tablets	***Currently in Shortage***
Remifentanil Injection	***Currently in Shortage***
Rifampin Capsules	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide (Ozempic) Injection	***Currently in Shortage***
Semaglutide (Wegovy) Injection	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***
Sterile Water for Injection	***Currently in Shortage***
Streptozocin (Zanosar) Sterile Powder	***Currently in Shortage***
Sucralfate Tablets	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Technetium TC-99M Mebrofenin Injection	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Teprotumumab-trbw	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injectable Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***